VOLUME 14 NUMBER 10

Food·Drug·Cosmetic Law Journal

OCTOBER · 1959

Human Biological Drugs and Basic Drug Research . . . LEROY E. BURNEY, M. D.

The Present Organization of the Canadian Food and Drug Directorate . C. A. MORRELL

Federal Narcotic-Law-Enforcement Policy in Relation to Drug Addiction . . ALFRED L. TENNYSON

See Table of Contents for Articles in This Issue

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $15 per year, including a handsome binder to hold one year's issues. Single copies are $1.50 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

October, 1959
Volume 14 • Number 10

Second-class postage paid at Chicago, Illinois.

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . October, 1959

		Page
Reports to the Reader About the Authors . . . Meetings		617
Christopher Comments . . .	Thomas W. Christopher	618
Washington—Action and News In the Food and Drug Administration		619
Human Biological Drugs and Basic Drug Research	Leroy E. Burney, M. D.	621
The Present Organization of the Canadian Food and Drug Directorate	C. A. Morrell	634
Federal Narcotic-Law-Enforcement Policy in Relation to Drug Addiction	Alfred L. Tennyson	639
Food Packaging and the 1958 Food-Additives Amendment	Charles W. Kaufman	649
Proposed Color-Additive Amendments to the Federal Food, Drug, and Cosmetic Act .	Fuller Holloway	657
The Projects of Uniform Food Codes in Latin America and in Europe	Julius G. Zimmerman	661
Opening of the Detroit Office of the Food and Drug Administration — Dedication of the George Potter Larrick Building	Edwin L. Harding	671
Foreign Law Comment	Julius G. Zimmerman	675

VOLUME 14 NUMBER 10

© 1959, Commerce Clearing House, Inc., Chicago 46, Illinois
All Rights Reserved

Printed in United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

Charles Wesley Dunn, New York City, *Chairman;* President, The Food Law Institute; Chairman, Division of Food, Drug and Cosmetic Law, ABA; Chairman, Section on Food, Drug and Cosmetic Law, New York State Bar; Public Trustee, The Nutrition Foundation; General Counsel, Grocery Manufacturers of America, Inc., and World Medical Association—United States Committee

H. Thomas Austern, Washington, D. C., *Vice Chairman;* General Counsel, National Canners Association

William W. Goodrich, Washington, D. C., Assistant General Counsel, United States Department of Health, Education, and Welfare

Robert E. Curran, Ottawa, Canada, Legal Adviser, Canadian Department of National Health and Welfare

Charles A. Adams, London, England, former Director, Food Standards and Labelling Division, United Kingdom Ministry of Food

Fred Bartenstein, Rahway, New Jersey, Counsel, Merck & Company, Inc.

Frank T. Dierson, New York City, Assistant General Counsel, Grocery Manufacturers of America

William E. Fairbanks, New York City, General Counsel, Thomas J. Lipton, Inc.

A. M. Gilbert, New York City, Counsel, Best Foods, Inc.

Robert S. Gordon, New York City, General Counsel, National Dairy Products Corporation

Edwin L. Harding, Battle Creek, Michigan, General Counsel, Kellogg Company

Harold Harper, New York City, General Counsel, National Wholesale Druggists' Association

James F. Hoge, New York City, General Counsel, Proprietary Association of America; Counsel, American Foundation for Pharmaceutical Education

Vincent A. Kleinfeld, Washington, D. C., former Food and Drug Law Attorney, United States Department of Justice

George Link, Jr., New York City, General Counsel, Charles B. Knox Gelatine Company, Inc.

Michael F. Markel, Washington, D. C., General Counsel, Corn Industries Research Foundation

Samuel A. McCain, New York City, General Counsel, Corn Products Refining Company

Bradshaw Mintener, Washington, D. C., former Assistant Secretary of Health, Education, and Welfare

Merrill E. Olsen, Chicago, General Counsel, Quaker Oats Company

C. Joseph Stetler, Chicago, Director, Law Department, American Medical Association

William N. Strack, Chicago, General Counsel, Swift & Company

Walton M. Wheeler, Jr., Indianapolis, General Counsel, Eli Lilly & Company

Edward Brown Williams, Washington, D. C., former Principal Attorney, United States Food and Drug Administration

Julius G. Zimmerman, New York City, Attorney, The Coca-Cola Export Corporation

THE EDITORIAL ADVISORY BOARD advises on policies, subjects and authors. It assumes no responsibility otherwise. Its members render this public service without compensation, in order that the FOOD DRUG COSMETIC LAW JOURNAL may comply with the highest professional standards.

Scientific Editor: Bernard L. Oser

Editor of Comments: Thomas W. Christopher

Editor of Cosmetic Law: S. L. Mayham

Editor of Canadian Law: Robert E. Curran, Q. C.

Editor of Foreign Law: Julius G. Zimmerman

REPORTS

TO THE READER

About the Authors

Six more papers from the 1959 meeting of the Division of Food, Drug and Cosmetic Law of the Section of Corporation, Banking and Business Law, American Bar Association, are presented in this October JOURNAL. The annual meeting was held on Monday, August 24, in the Balmoral Club of the Balmoral Hotel, Miami Beach, Florida, in two sessions—one in the afternoon and one in the evening.

Leroy E. Burney, M. D., presented a special address on "Human Biological Drugs and Basic Drug Research." Dr. Burney is Surgeon General of the United States Public Health Service.

The Canadian Food and Drugs Act was discussed by **C. A. Morrell,** who is director of the Food and Drug Directorate, Canadian Department of National Health and Welfare.

Alfred L. Tennyson, Chief Counsel in the United States Bureau of Narcotics, spoke on the subject of the federal narcotic law—specifically, "Federal Narcotic-Law-Enforcement Policy in Relation to Drug Addiction."

At the dinner meeting there were two panel discussions—on the 1958 food-additives amendment to the Federal Food, Drug, and Cosmetic Act and on the proposed color-additive amendments to the Act. One paper from each of the panels appears in this issue. From the food-additives group, there is a paper by **Charles W. Kaufman,** director of research and development of the National Dairy Products Corporation and president of The Packaging Institute. The color-additives amendment paper is by **Fuller Holloway,** general counsel of The Toilet Goods Association.

The sixth of the ABA papers is a study by **Julius G. Zimmerman,** an attorney, of New York City. Dr. Zimmerman presents an analysis of "The Projects of Uniform Food Codes in Latin America and in Europe."

Edwin L. Harding, vice president and general counsel of the Kellogg Company, Battle Creek, Michigan, reports on the opening of the Detroit office of the United States Food and Drug Administration on May 14. The headquarters was named the "George Potter Larrick Building," to honor the Commissioner of Food and Drugs, who has headed the FDA since 1954.

Also in this JOURNAL are the features "Christopher Comments," written by **Thomas W. Christopher,** who is associate dean and professor of law at Emory University Law School, Atlanta, Georgia, and "Foreign Law Comment," contributed by Dr. Zimmerman.

Meetings

FDA-FLI Joint National Conference.—The program has been announced for the 1959 joint national conference of the Food and Drug Administration and The Food Law Institute. It will take place in the auditorium of the United States Department of Health, Education, and Welfare, at Washington, D. C.,

on November 16-17. The objective of the conference is the discussion of food additives and other major food problems arising under the Federal Food, Drug, and Cosmetic Act.

The FDA will present the morning session on November 16, with introductory statements by Secretary of Health, Education, and Welfare Arthur S. Flemming and by Charles Wesley Dunn, president of The Food Law Institute; industry will take over for the afternoon session. The morning session on November 17 will be slanted to consumer problems; that afternoon will be devoted to a panel session. There will also be an informal panel discussion of *questions* submitted to the conference or presented by panel members.

The following organizations are cooperating in the conference: The Food Protection Committee of the National Research Council; the food-additives committees of the Manufacturing Chemists' Association and the Institute of Food Technologists; The Nutrition Foundation; and The Packaging Institute.

Conference—Pure Food Centenary, 1960.—A conference will be held in London, England, September 20-23, 1960, to celebrate the centenary of the "Act for preventing the Adulteration of Articles of Food and Drink." Administrators, scientists and food manufacturers from Great Britain and abroad will attend.

The proceedings will begin with a reception given by the British Government at Lancaster House on September 20. During the conference, which will have its headquarters at the Royal Institution of Great Britain, meetings, lectures, an exhibition and laboratory visits will demonstrate the progress achieved during the past 100 years and show the part which the food chemist plays in improving the quality of food and providing better nutrition and better health. A number of outstanding speakers have already accepted invitations to read papers at conference sessions. Interested persons are asked to write for full details and registration forms to The Secretariat, The Pure Food Centenary, 14, Belgrave Square, London, W. 1, England.

Association of State and Territorial Health Officers.—Dr. Wilson T. Sowder, state health officer of Florida, was elected president of the Association of State and Territorial Health Officers at the final session of their annual meeting, at Washington, D. C., on October 16. Dr. Sowder succeeds Dr. D. G. Gill, state health officer of Alabama. Other officials elected at the meeting include Dr. Mack I. Shanholtz, Commissioner of the Virginia Department of Health, vice president, and Dr. Andrew C. Offutt, Commissioner of the Indiana Board of Health, secretary-treasurer.

Among major recommendations were suggestions concerning toxicity of herbicides, poliomyelitis-vaccine policies, public-health studies of radiation-control programs, and fluoridation of public water supplies.

CHRISTOPHER COMMENTS

Thomas W. Christopher is associate dean and professor of law at Emory University, Atlanta, Georgia.

Libel Against Government Employee.—A United States Supreme Court decision * rendered in June deals with the liability for libel of a

(Continued on page 677)

* *Barr v. Matteo*, 79 S. Ct. 1335 (1959).

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

New Division Appointments Announced.—Appointment of Chester T. Hubble as head of a new Division of Administrative Review in the Food and Drug Administration's Bureau of Enforcement was announced on October 23 by Malcolm R. Stephens, director of the bureau. Mr. Hubble has been assistant to the director of the bureau since January, 1957.

The new division comprises the food branch, the drug-and-device branch and the stenographic branch of the bureau. It was created to provide better general supervision and control in the administrative review of proposed legal actions and in handling correspondence concerning requirements of the Federal Food, Drug, and Cosmetic Act and related acts.

Mr. Hubble started his FDA career as a seafood inspector at New Orleans in October, 1934. He has served as a food and drug inspector in the St. Louis, Chicago, New Orleans and Minneapolis districts, and was Chief Inspector of the latter two. He became District Chief at Minneapolis in 1945 and at Cincinnati in 1951. He holds an A. B. degree from Central College, Fayette, Missouri, and an M. A. degree in chemistry from the University of Missouri.

Ralph F. Kneeland will be in charge of the food branch of the division and Morris Yakowitz will be in charge of the drug and device branch, which will also handle cosmetic cases, Mr. Stephens said.

Mr. Kneeland entered the Food and Drug Administration as a food and drug inspector in 1935, after receiving a B. S. degree from the Massachusetts State College and an M. S. degree from the University of Delaware, both in chemistry. After inspection assignments at Philadelphia, Boston, Seattle and Portland, he was transferred to the administrative offices in Washington in 1939.

Mr. Yakowitz entered FDA as a chemist in 1935, serving in analytical work in the San Francisco laboratories, and was chief drug chemist there prior to his transfer to Washington headquarters in 1948, where he has specialized in the review of drug, device and cosmetic cases. He holds a B. S. degree in chemistry from Johns Hopkins University and did graduate work at the University of California.

Proposal for Heptachlor Ban.—The Food and Drug Administration on October 27 issued a proposal to rescind its present regulation on the use of the pesticide heptachlor on certain food crops—an action which would ban any amount of residue of heptachlor in or on foods shipped in interstate commerce. Small residues—one tenth of one part per million—are permitted on harvested fruit, vegetable, grain and forage crops

at present. The new action proposes a zero tolerance for residues of the pesticide, which is widely used on crops during the growing season.

The proposal follows disclosure of new scientific data showing that an oxidization product of heptachlor—heptachlor epoxide—forms on crops, largely as a result of weathering. Residues of the epoxide on crops have heretofore gone undetected because the analytical method for detecting the product differs from that used to find heptachlor. Recent FDA studies have shown that such residues are likely to be present on crops, even though farmers follow official recommendations for applying heptachlor. Epoxide residues are also deposited in meat and milk when forage containing the epoxide residue is fed to meat and dairy animals.

According to available animal test data, FDA stated, the epoxide appears to be more acutely toxic than heptachlor. The agency explained that long-term testing and evaluation of results to prove the safety of combined residues of heptachlor and its epoxide have not been completed. This latest action was taken as a preliminary step in eliminating any residue of heptachlor or the epoxide on crops for which heptachlor has been permitted.

Within 30 days after publication of this proposal (also on October 27), according to FDA, manufacturers who have registered a product containing heptachlor or heptachlor epoxide with the United States Department of Agriculture or who have applied for a registration may request referral of the proposal to a scientific advisory committee.

Written comments from other interested persons may be filed with the Hearing Clerk of the Department of Health, Education, and Welfare—also within 30 days.

On October 21, the Food and Drug Administration announced a change in its coal-tar color regulations to provide cutoff dates for inventories of colors that are no longer certified for use in the manufacture of foods, drugs and cosmetics. The order published the same day in *Federal Register* involves six coal-tar colors recently removed from a list certified by FDA as harmless and one other color for which manufacturing specifications have recently been changed. Cutoffs, or revocation dates of FDA certificates, will also be provided for colors delisted in the future.

Heretofore, delisting actions have not prohibited sale or continued use of batches of colors previously certified by FDA. Under the new regulation, removal of a coal-tar color from the list of permitted colors prohibits future sales or use of that color in products for which it was formerly certified, FDA explained. Products made with the banned colors after specified cutoff dates will be considered adulterated and, thus, illegal under the Federal Food, Drug, and Cosmetic Act.

On the other hand, products made with FDA-certified colors prior to the cutoff dates will not be considered adulterated—even though they may contain the banned colors—unless it is determined that existing stocks cannot safely be used, FDA noted. In the latter event, special regulations covering the situation will be issued.

The October 21 announcement does not specify a cutoff for 17 lipstick colors recently removed by FDA from the list of colors allowed for human use. On these the time limits within which appeals can be filed have not elapsed.

Cutoff dates for the seven colors named in the new announcement are as follows: (1) January 1, 1960—for all certificates issued for existing batches and portions of batches of FD&C Orange Nos. 1 and 2, FD&C Red No. 32 and FD&C Yellow Nos. 1, 3, and 4 before these colors were removed from the list and (2) January 15, 1960—for all certificates issued for existing batches and portions of batches of FD&C Red No. 1 that do not comply with new specifications published in the *Federal Register* of July 16, 1959.

Vol. 14, No. 10 October, 1959

Food·Drug·Cosmetic Law
Journal

HUMAN BIOLOGICAL DRUGS AND BASIC DRUG RESEARCH

By LEROY E. BURNEY, M. D.

The Surgeon General, United States Public Health Service, Addressed the Annual Meeting of the Division of Food, Drug and Cosmetic Law, American Bar Association, at Miami Beach, August 24, 1959

I AM VERY GLAD that I can answer "present and accounted for" on this platform today. Once before when your distinguished chairman presented me with a summons to this annual program, I was unable to honor it. Since then I have not been certain whether he would send a marshal after me or—worse still—would not give me another chance. But with his accustomed tact, Mr. Dunn has bided his time and now has given me the tempting subject of scientific research and the development of biological and other drugs.

The subject is tempting not only because the vistas of future progress in biological and drug therapy appear limitless, but also because it gives me an opportunity to tell you something about the policy of the Public Health Service in this rapidly expanding field. Developments of recent years strongly suggest that lawyers, medical scientists, and research administrators will need increasing understanding of one another's objectives and problems. If practicing physicians and the public are to receive the full benefit of medical research, they will need our mutual understanding and cooperation.

Evolution of Drug Research

In order to appreciate more fully the present status of drug research, we have only to consider the resources of the physician at the beginning of the present century. Although synthetic chemistry had begun to make available a wider range of drugs affecting the central nervous system, as well as refined products of digitalis and cinchophen, the American physician in most instances could not treat disease. He could treat symptoms but, except in the case of diphtheria antitoxin, he had no specific therapy in the presence of disease. Preventive therapy was nonexistent, except in the use of smallpox vaccine and the uncertain use of diphtheria antitoxin to provide a brief immunity in exposed individuals.

Moreover, the few biologic products and the basic drugs then in use were not readily obtainable in standard purity and potency. The pharmaceutical industry as we know it today was in its infancy. Ethical manufacturers in the United States had to compete, on the one hand, with European patents and, on the other, with a seemingly endless stream of so-called "patent medicines" produced in this country and marketed without quality controls or proper labeling. The deep-seated fears of an ignorant population, the helplessness of physicians, and the undeveloped state of American medicine all contributed to the widespread use of these worthless nostrums.

As this audience knows, two national laws were enacted in the first decade of this century which were to afford strong protections for ethical manufacturers and the public. The first, enacted in 1902, gave to the Public Health Service the responsibility for licensing the production of biologic products moving in interstate and foreign commerce. The second law affecting the pharmaceutical industry was the Pure Food and Drugs Act of 1906, the administration of which was initially under the Department of Agriculture. Both these laws have been modified over the years and in both instances new substantive legislation was enacted, but the basic provisions with respect to human biological products and drugs remain the same. It can be said—I believe—without question that the establishment of these programs by the United States Government in the early years of this century provided a stimulus and a sound foundation for the ensuing growth in volume, strength and world-wide reputation of the American pharmaceutical industry.

Underlying the weakness of medicine and pharmaceutical production at the turn of the century, however, was the embryonic state of scientific research in the United States. Our few university-affiliated medical schools depended upon European science for any advances in basic knowledge, and this dependence was to persist unrelieved until after World War I. Even then, it was not until after World War II that any substantial expansion of basic medical research occurred. Nevertheless, American science at an early stage showed a remarkable aptitude for applying fundamental knowledge and research methods. As a result, many contributions were made to scientific understanding in the field of microbiology, as well as to the development of improved instrumentation for the observation of biological phenomena, new and improved therapeutic agents, and surgical procedures. Also, prior to World War II, American medical science had made some notable contributions to fundamental knowledge, especially in the fields of biochemistry, genetics, virology and endocrinology. These beginnings were the groundwork for future major advances.

During the same period, the pharmaceutical industry supported some research in medical schools and other university departments. As a rule, this support was in the practical area of developmental research or clinical trial of new products. The industry itself conducted very little basic research, like medicine's relying upon European science for the fundamental knowledge that is the beginning of all practical advance.

Today, the practicing physician has at his command a wealth of biological and pharmaceutical products manufactured by exacting processes to ensure quality control, and in quantities that make them readily available to physicians throughout the country. He no longer treats only symptoms; he can prevent or treat effectively a wide range of diseases which were completely beyond the reach of medicine in 1900. Preventive biologicals are available for many more infectious diseases, and effective chemotherapy is now available for practically all bacterial infections, as well as for some helminthic diseases. Synthetic vitamins and hormonal preparations make it possible to combat an increasing range of deficiency diseases and endocrinal disturbances. Advances in hematology and virology have further increased the physician's armamentarium, with blood products and new virus vaccines.

It would be difficult, if not impossible, to distinguish all of the forces that have brought about extraordinary advances during the past

20 years in human biologicals and pharmaceutical products. Many have called these two decades the period of greatest medical progress in recorded history, and have attributed that progress to the development during World War II of a mobilized approach to human biological and drug research under governmental auspices with the participation of industry, public and private nonprofit institutions.

There is no doubt that this wartime speed-up afforded medicine and public health many practical advantages in the form of new or improved vaccines, new drugs, insecticides, and blood products. Much important basic work had to be set aside, however, and medical scientists throughout the country were the first to insist that our wartime progress rested on fundamental discoveries of a preceding period. They stimulated the recognition by the American people that never again could our country safely ignore the need for sustained, augmented basic medical research.

Thus the discovery and development of drugs is only a part of the medical research story. The Nation's investment in medical science has increased enormously. It involves many sources of support—private foundations, voluntary agencies, industry, the United States Government, and a growing number of state and municipal governments. Many of the Nation's universities and medical schools invest part of their endowments in scientific research. The objective of this great national effort is to increase scientific understanding of man as a biological organism, in sickness and in health; in all the stages of his growth, development, aging and dying; in all manner of environment to which he is exposed, on earth and in space travel.

The practical means to prevent disease, to cure it, to ameliorate it, or simply to relieve pain are a part of, and indeed flow from, this scientific effort. But medical science is not only an explorer of man's life processes and not only a discoverer of diagnostic and therapeutic agents. It is also the guardian of human life and well-being, and in this present era of rapid industrial development, medical science pleads the cause of human biology at the bar of technological progress.

There is need for this plea. Science and technology have introduced new physical and chemical forces of great power into the environment—and will continue to do so. The tendency is to concentrate on the unquestioned material benefits of such advances, but without due regard for their potential effects on human life. Under such circumstances, it is all the more essential that medical science keep watch

over the biological effects and sound the needed warnings. Hence, the national medical research effort emphasizes its basic mission—the study of man.

Medical Research in Public Health Service

The Public Health Service's interest in medical research begins and ends in pursuit of the same mission. Our programs at the National Institutes of Health represent about 70 per cent of the investment by the United States Government in medical research, and nearly 40 per cent of the Nation's total investment in this field. We conduct research directly in our own laboratories and clinical center, and we support research and training in nonfederal laboratories through research grants and contracts. Inherent in these programs are policy problems important to government and to industry.

The support of the Nation's total medical research effort is about equally divided between federal and nonfederal sources. National expenditures for medical research during the past decade have increased from $133 million to $575 million. Federal expenditures during the same period advanced from $51 million to $295 million, of which $212 million is represented by programs of the National Institutes of Health. Approximately three fourths of the research funds administered by the Public Health Service are awarded in grants and contracts to medical schools, universities, and other nonfederal institutions.

Public Health Service Advisory Groups

The medical research programs of the Public Health Service are developed and conducted under the guidance of a series of national advisory councils established or authorized by the Congress. The councils are composed of nonfederal leaders in science and public affairs, with ex-officio representation of other federal agencies having related research programs. In addition to their basic responsibility for advice in the formulation of research and training policies, the councils also review applications and recommend the award of research grants. As Surgeon General, I am authorized to veto a grant recommended by the council, but I may not reverse a council's disapproval. To provide the councils with needed technical information in a very wide range of scientific specialties, panels of scientists drawn mainly from universities are relied on by the National Institutes of Health. These study sections make the initial review of applications from the

viewpoint of experts in the applicant's field, and they work closely with the scientific staffs of NIH.

This procedure for approval of grants does not apply to research contracts. The institutes have at present a total of 144 contracts, largely with academic and industrial groups, for the conduct of specific activities in several programs. These contracts are negotiated by NIH personnel with the aid of consultants from nonfederal organizations. In the field of cancer, a subcommittee of the National Advisory Cancer Council is concerned with institute policy regarding both grants and contracts for cancer chemotherapy. I believe these various procedures add up to a flexible and efficient way of supporting research.

Basic and "Engineered" Research Programs

The programs conducted at NIH, as you know, are organized on the basis of disease categories, in accordance with Congressional legislation and appropriations. But successful research into the causes of disease has frequently come from the most unexpected quarters and has often been pioneered by investigators whose work at the time was unrelated to any particular disease. For this reason, the funds appropriated for categorical purposes within the various institutes actually support many diversified programs in the basic medical sciences.

As new knowledge emerges from the basic projects and clear lines of attack against diseases are indicated, laboratory and clinical investigations will be supplemented increasingly by large-scale collaborative studies with precise objectives and rigid protocol. This is sometimes known as "engineered research." The Public Health Service has already served as a central point for the design and execution of studies of this type.

Cancer Chemotherapy Program

To intensify the search for drugs that can reach and destroy malignant cells wherever they may be in the body, the Public Health Service operates the Cancer Chemotherapy National Service Center. The service center, as part of the National Cancer Institute, co-ordinates the chemotherapy interests of the Public Health Service, the Veterans' Administration, the Food and Drug Administration, the Atomic Energy Commission, and two nonfederal agencies—the American Cancer Society and the Damon Runyon Memorial Fund for Cancer Research.

Some of the Nation's leading research institutions and pharmaceutical, chemical and allied industrial concerns are taking an active part in this program. Working under contracts with the service center, these organizations supply materials for anticancer screening, develop screening techniques, and produce large quantities of materials which are selected for clinical trial. Since the inception of the center four years ago, some 50,000 agents have been screened and over 50 have been tried clinically. Of these, at least 20 are temporarily effective against many forms of cancer. At present, about 175 hospitals are conducting clinical trials, with 4,000 to 5,000 patients receiving treatment under careful medical supervision at any one time.

Psychopharmacology Program

A similar program is conducted by the National Institute of Mental Health. Since little is known concerning the mechanisms of action of such agents as the tranquilizers and energizers, much of the support in this field must be given to basic research. The Psychopharmacology Service Center was established four years ago to assist in the development of sound research programs on drugs used in the treatment of mental illness. Much of this work is being done in universities and medical schools through grants. The subjects of this research range from biological problems at cellular and subcellular levels to observations on the effects of drugs on the behavior of human beings.

Biologicals Development

Although by no means as extensive in scope and volume as the growth of drug research, biologicals development in the United States has advanced strikingly in the past two decades. Progress has been along two lines, namely, the application of new fundamental knowledge to the improvement of older products and the development of new products. At the present time, more than 1,200 separate product licenses are in effect for 275 specific products manufactured by 176 licensed establishments. All but a very small proportion of the Nation's supply of biologicals is produced and distributed by the pharmaceutical industry.

The first product licensed by the Public Health Service was smallpox vaccine, available through licensed establishments since 1904. Although smallpox occurs only rarely in those areas of the world where vaccination is widely practiced, it remains a hazard to mankind. Three factors account for this continuing risk. The disease has a high

prevalence in certain areas of the world, frequently rising to epidemic proportions. The speed of rapid international transportation, coupled with a fairly long incubation period, makes it easy for unrecognized cases to be introduced into susceptible populations. The failure of many adults to recognize that one successful vaccination does not necessarily give lifetime protection is a third factor in the international transmission of the disease.

The World Health Organization has adopted as one of its worldwide goals the eradication of smallpox. The development of dried smallpox vaccine will be an important factor in facilitating the World Health Organization's program. It will not be accomplished by intensive vaccination in endemic areas alone. Every country should use every means at its disposal to stimulate all of its citizens to maintain a satisfactory smallpox immunization program. As you know, the United States requires that every person entering our international airports and seaports or crossing our international borders have satisfactory evidence of recent vaccination. The Public Health Service has worked with the United States Department of State, travel agencies, and international transportation businesses to encourage American citizens planning foreign travel to be vaccinated before leaving the country.

Vaccines for the prevention of viral diseases, except in the case of smallpox, constitute the most difficult problem in the development and production of biologicals today. Despite the tremendous advances in the propagation of viruses within the past decade, these little-understood organisms are not as amenable to the development of safe and effective vaccines as are the larger micro-organisms. We still have no preventive human vaccine against rabies, and our therapeutic vaccine still leaves much to be desired. Techniques have not yet been developed whereby the hazards of the infectious hepatitis agent in human blood and plasma can be eliminated.

The growth of the American pharmaceutical industry in its capacity and competence to produce virus vaccines, however, gives promise that these and similar problems eventually will be solved. This progress was well attested by the response of the industry in the development of Salk vaccine in 1955 and of Asian-influenza vaccine in 1957.

In fact, the formalin-killed poliomyelitis vaccine originated by Salk and licensed in 1955 is one of the most difficult biological develop-

ments ever achieved. The Public Health Service has used every means at its disposal to promote a three-dose schedule of poliomyelitis vaccination for every American under 40 years of age—those in the most vulnerable age groups—yet there are at present approximately 40 million such individuals who have not received any vaccine at all or have received less than the recommended three doses.

At the present time, there is much interest in the potential development of attenuated live poliovirus vaccines for administration by mouth. Medical scientists have long believed that such vaccines would afford an active immunity similar to that imparted by an attack of the disease itself and, hence, of prolonged or even permanent duration. Other advantages visualized in oral live poliovirus vaccines are the ease of administration and, presumably, lower production costs. The crucial problem, however, is that the attenuated virus strains in live-virus vaccines might acquire virulence in vaccinated persons and that such individuals could then transmit severe poliomyelitis disease to susceptible contacts.

The Public Health Service is in close touch with these developments through its Division of Biologics Standards and a special committee of experts from research institutions in various parts of the country. At a meeting early in August, our committee had considerably more information on which to base its discussions than in the past, but the experts again pointed out the major problems which must be solved before these vaccines can be considered for general use in the United States. The scientists who have independently developed these vaccines and brought them to the point of large-scale field trials in certain parts of the world are well aware of the problems and are pushing toward their solution.

All the evidence thus far indicates that within a few years one or more oral live poliovirus vaccines probably will be under mass production and distribution in this country. Meanwhile, the Public Health Service intends to continue pressing for the use of every dose of Salk vaccine that can be produced, since it has proved its effectiveness in reducing the risk of contracting paralytic polio. The public health aim is now, and will be, to use every safe and effective means at hand to combat this disease.

Public Interest

The formulation of policies for the use of discoveries made in the medical sciences by investigators whose work is financed by Public

Health Service funds presents complex problems. These difficulties arise from the facts that some of these discoveries may be patentable and that Public Health Service programs provide a variety of ways by which federal funds are used to support research in this country and abroad.

The Public Health Service operates under the patent policy of the United States Department of Health, Education, and Welfare. The policy is designed to safeguard the interests of the American people in their large public investment in medical research; to encourage individual and cooperative achievements in this field; and to establish procedures for determining patent rights and obligations. The basic policy and rules—covering discoveries by Public Health Service employees, grantees and contractors—were promulgated in 1955. A special policy relating to cancer chemotherapy discoveries was promulgated in 1957 and revised in 1958.

In so far as scientific discoveries made by Public Health Service employees, grantees and contractors are concerned, the public interest will usually be ensured simply by the publication of findings. This method of disseminating scientific information is in accord with the general policy of the Department, which holds that the results of research in which the Department has a financial interest should be made available promptly, widely and freely to other scientists. The Department takes the position that this availability can generally be achieved through publication, which, in effect, dedicates a government-owned invention to the public.

In some instances, however, the public interest may call for patenting. When patent applications are filed for discoveries by Public Health Service scientists, the patent is government-owned and licenses issued under the rights are royalty-free, revocable and non-exclusive. In some situations, the Department's policy permits a grantee or contractor to retain patent rights, providing that there are adequate safeguards against unreasonable restrictions or excessive royalties and that the government receive a royalty-free license with a right to issue sublicenses for governmental purposes. Some non-profit research institutions in the United States have patent policies in accord with that of the Department in safeguarding the public interest. In such cases, the institution may obtain patent rights for its scientific discoveries made with financial support from the Public Health Service.

The Department's policy on cancer chemotherapy patents was revised in 1958 in an effort to encourage industrial participation in the activities of the Cancer Chemotherapy National Service Center. The chief difference between this and the general rule concerning contracts is the right of an industrial contractor to retain patent rights, subject to the so-called "march in" provision. The "march in" is intended to make sure that any manufacturing contractor who develops a useful anticancer substance will supply to the public adequate quantities of the material at a reasonable price. Should he fail to do so, the Surgeon General of the Public Health Service has the right to authorize additional manufacturers to produce under the patent or to require the primary contractor to authorize such additional production. The revision of 1958 provides procedures designed to protect the owner of the patent against arbitrary exercise of the "march in" rights.

The idea of the government's taking a hand in the development of new products under contract has been disturbing to industry. This is an understandable reaction. The co-ordinated wartime effort was viewed as an emergency measure, and American industry has never failed to rise to the Nation's needs in an emergency. The freedom of industry to develop, produce and market exclusive products by processes protected under patented rights is a central factor in our American concepts of private enterprise and should be preserved. Moreover, contractual arrangements with government in peacetime implied to some manufacturers a type of control incompatible with those concepts—that is, control in the areas of patents and prices. Such control should be viewed as potential rather than as actual. The scientific, administrative and legal staffs of the Department of Health, Education, and Welfare are confident that the "march in" provisions of the patent policy will rarely, if ever, need to be invoked.

It must be said, in candor, that this new relationship did not materialize overnight or without difficulty. During the past few years, the Public Health Service and the industries concerned with biologicals and drug research and development have been experiencing a valuable learning process. I shall be frank in admitting that our organization understands industry's position and problems much better. I believe that industry understands us better. The evidence of this mutual growth in understanding and confidence is the fact that since the procedural aspects of the Department's patent policy were revised in 1958, no less than 35 industrial firms have accepted contracts with the Cancer

Chemotherapy National Service Center. I believe we have a sound basis for achieving great advances in this and other fields.

Conclusion

In sum, it is safe to predict that the development of new drugs and biological products will accelerate rapidly in the next decade. As indicated at the beginning of this paper, the substance of medical progress is the work of medical scientists in laboratory and clinical investigations, but administrators and lawyers also have important parts to play in the oncoming advances. For it is certain that the production and ultimate use of these valuable products will depend upon decisions and administrative action at policy-making levels, as well as upon scientific and technical accomplishments.

The role of the United States Government—specifically, of our Department of Health, Education, and Welfare—in the rapidly expanding field of human biologicals and drugs rests, I believe, on one central fact: In this period of revolutionary scientific change, neither industry alone nor government alone is big enough to bring the results of medical research out of the test tubes to the hands of every physician in the form of safe and effective pharmaceutical agents for his patients.

The modern methods and technical equipment for research and development in these fields are complex and costly beyond the imagination of earlier generations. As research technology advances, methods and facilities will grow more complex and costly. The substances with which we are dealing today are far more potent and complex in their effects upon the human organism. We need much more basic knowledge concerning the very complicated responses of human cells and human tissues to the onslaught of synthetic and radioactive substances, and to biological products derived from the tissues of other animal species.

We need also to place the Nation's great scientific and technical resources behind the search for new and improved pharmaceutical products. We need, above all, to submit our day-to-day hopes for new "miracles" to biological judgments. There is much more at stake than the reputation of a governmental agency, an industry or an individual scientist. Human life itself is at stake. If industry and government cannot work closely together with each other and with the Nation's scientific institutions in the development of safe and effective pharmaceutical agents, the cause of health progress—in which the American

people have invested so heavily and are prepared to invest even more generously—is lost.

Over the years, the Public Health Service and the pharmaceutical industry have developed a *modus operandi* which has served the public well in our joint responsibility for biologics standards. A similar relationship exists between the Food and Drug Administration and industry in the introduction of new drugs. I believe that our new relationship in programs of research and development will be strengthened by the earlier experience and that the old relationship will be made more fruitful by the new. Let us move ahead with confidence that our combined efforts will bring great benefits to human life and health.

[The End]

• COURT ACTIONS DURING SEPTEMBER •

Twenty actions against warehoused foods covered more than half the volume of unfit foods seized during September—193 out of 346 tons—the Food and Drug Administration has reported. Insect contamination and live infestations were found in shelled peanuts, flour, egg noodles, rice, prepared baking mixes, and a breakfast cereal. Spoilage was discovered in salad dressing and in seafoods, including fillets of cod and perch and frozen lobster tails.

Of the remaining unfit foods seized, 55 tons consisted of insect-infested peanuts and pistachios and 49 tons of rodent- and insect-contaminated wheat, rice, flour and corn meal. Ten tons of so-called "fancy" tomato paste contained fly eggs and maggots, and the paste was alleged to have been prepared and packed under unsanitary conditions. Seven tons of dried blackeye peas were insect-infested.

The following foods were seized as economic cheats: three and one-half tons of imported coca powder in which cocoa shell had been substituted for cocoa; an instant coffee containing dextrose in place of coffee; "chocolate" fudge cookies made with cocoa rather than chocolate; canned peaches labeled as "irregular slices in heavy syrup" which were actually irregular sizes and shapes in light syrup; and short-volume cans of salad and cooking oils.

Of 24 drugs and devices seized during September, 16 were alleged to be misbranded by false and misleading claims. Five shipments of a so-called "breast developer" were seized at Tampa and Clearwater, Florida. The action filed in the federal district court charges that this device will not increase the size of a woman's breast and that it is a hazard to health as well as a fraud.

Mineral bath salts were offered at $9.95 for a three-pound package to treat objectionable body odor; brighten the eyes; and build up resistance to diseases such as rheumatism, arthritis, high blood pressure, ulcers, Buerger's disease, female disorders, and stomach and intestinal ailments.

THE PRESENT ORGANIZATION of the Canadian Food and Drug

The Head of the Food and Drug Directorate, Canadian Department of National Health and Welfare, Presented Data Concerning His 314-Member Organization at the American Bar Association Meeting, Held at Miami Beach on August 24

IF the Canadian Food and Drug Directorate is to exercise its proper influence in terms of consumer protection against health hazards and fraud in the consumption and sale of foods, drugs, cosmetics and medical devices it must continually strive for a greater measure of efficiency in its work. For the benefit of this United States audience, it should be noted that the Canadian Food and Drugs Act covers very much the same field as the Federal Food, Drug, and Cosmetic Act of the United States. The authority of our food and drugs act is not limited to products in interprovincial commerce, and it covers advertising as well as labeling. These latter responsibilities result in a great deal of work. There is also the licensing and administrative control of biological products and some groups of patent medicines under the act and the Proprietary or Patent Medicine Act which is also enforced by the directorate.

Those who are familiar with the work of the United States Food and Drug Administration will know a great deal about our problems in Canada because they are the same as, or similar to, problems dealt with by the FDA. Naturally, when making any comparisons one will remember that the United States has ten or 11 times the population of Canada and that the number of manufacturers, retailers and wholesalers to be dealt with in the United States is greater.

However, an examination of the quantity and variety of work that presents itself to us in the ordinary course of events leads to the conclusion that it is very large when compared with the number of people we have to deal with it. As a consequence great care must be taken to limit our activities to those that will be most effective. To accomplish this, a reorganization has been recently approved by the department and the civil service commission, which will establish a

Directorate

By C. A. MORRELL

senior officer as head of a program-planning branch which will also study, analyze and record the effectiveness of our work in terms of both educational and enforcement activities.

While program planning has not been neglected in the past, it has been carried on by a committee consisting of the director, assistant directors and regional directors, all of whom have many other duties. No one of these officers has been able to devote more than a small portion of his time to the study of future plans and the effectiveness of past activities. The results reported at our annual directors' conferences have shown a lack of conclusiveness or even that plans have been abandoned or become distorted because they were not based on sound or complete information. It is expected that this obvious and serious weakness in our work will be removed when the new branch is able to recruit sufficient staff and has been at its business for a few years. I say "a few years" because of some conception of how much is to be done by this new branch in collecting and analyzing information and statistics. The American Food and Drug Administration has conducted such work for a number of years and it is to be hoped that it will be possible for us to benefit in some way from their experiences.

Employees—Distribution and Duties

A few words on the present organization of the Canadian Food and Drug Directorate may be of interest to you.

The present organization consists of 314 people distributed throughout Canada, about half of whom are in Ottawa. I am hoping that this number will be increased a bit in 1960.

Ottawa is the home of the national headquarters, and our staff there is housed in a modern building (3½ years old), which was built

expressly for the purpose. It consists of a laboratory building with an air-conditioned biological wing, a business administration building also housing the library, and an administrative building—all of which are joined together for convenience and ready access. Although the space provided was considered large for our needs when it was planned, there are some signs now of a little crowding in places.

The senior officers in Ottawa include the director, associate director, two assistant directors, a chief medical officer and a chief administrative officer.

The associate director is the officer now charged with program planning. Except for acting on behalf of the director when necessary, that will be his function.

One assistant director is in charge of the scientific services, which means that he directs the work of the ten sections of the laboratory in Ottawa and is responsible for supplying advice on technical and scientific matters to the director and other officers. He acts also in an advisory capacity to the regional laboratories. Most of the research and investigative work necessary in our administration is carried out in our Ottawa laboratories.

The other assistant director is in charge of inspection and enforcement services. Under him he has a food unit, a drug unit and an enforcement unit. The food and drug units prepare correspondence concerning labeling, advertising and inspection activities, and review labels and the advertising for foods and drugs carried in all media—for example, TV, radio and newspapers. They also collect information on inspection programs. The chief enforcement officer is responsible for reviewing recommendations from the field officers in respect to prosecutions, seizures, warnings, etc., and for maintaining liaison with the legal branch of the department. It is his duty also to expedite in any way possible to him the processing of legal activities.

The chief administrative officer is responsible for the business affairs of the directorate, such as budget matters, clerical and stenographic pools, records, forms, purchasing, stores, maintenance, etc.

Because we are enforcing a consumers' act we have recently established a consumer section. It is the function of the chief of this section to develop and maintain contact with consumer groups in Canada, to give and receive information pertinent to our activities and to determine what are the complaints and wishes of consumers.

All of these officers report to the director, who, in turn, reports to the deputy minister of health. The latter is the highest permanent officer in the department and is responsible to the minister of national health and welfare, who is a member of the cabinet. All policy matters are decided at Ottawa, and general direction stems from there.

Field Operations

In respect to the field staff, Canada is divided into five regions. These are comparable to the 17 districts of the FDA. Each of these regions has a headquarters with a regional director; a laboratory; and inspection and administrative services. Since Canada has a very large area, each of these regions is quite large and, for better contacts and prompt enforcement, there are 21 district offices in the regions. Each district office reports to the appropriate regional director.

The great bulk of the enforcement work is carried out in the district offices and regional laboratories and offices. They are responsible for inspection of factories and retail and wholesale establishments; for examination of import shipments; for collection and analysis of samples from imports and domestic sources; and for dealing directly with the trade and public and with other government departments at the local level.

Imports Subject to Impartial Enforcement

The decisions and actions of the food and drug directorate will have some effect on United States and other foreign businesses selling foods or drugs in Canada. The laws which are enforced by the directorate apply to products coming into Canada from abroad, as well as those made at home. Enforcement must be impartial, and no concessions can be made to imports that cannot be made in the case of domestic products. Apart from the impropriety of doing so, you will understand that Canadian manufacturers would be quite justified in taking strong measures against any unfair relaxation of our requirements that would favor foreign competitors' products or give them any advantage over our own. The food and drug officers have always treated imports in the same way as Canadian products, and will continue to do so.

In this connection I should like to point out that we in the Canadian Food and Drug Directorate are now giving consideration to recommending amendments to the food and drug regulations concern-

ing the method of declaring information on the labels of food products. We have not been satisfied that such information as the net contents of packages or the common name of the food and other information required by the law has been clearly and conspicuously presented. Indeed, in our experience with food packages sold in Canada, the prominence of this information in many cases has become less and less and is now difficult to find on some products. We hope to have a proposed regulation drafted shortly that will give the manufacturer and our officers a more definite guide as to what "clear and conspicuous" means.

Such a regulation will surely require that many labels now being used on food in Canada will have to be revised. This will mean that some United States labels now being used for Canadian exports will need revision also. United States and other foreign manufacturers will, of course, be given the same reasonable time to make these adjustments as are those in Canada, but they will have to comply with the requirements along with all others. **[The End]**

OCTOBER REPORT—VOLUNTARY CORRECTIVE ACTIONS IN FOODS AND DRUGS

Nineteen individual plant improvements costing $41,167 were made voluntarily by food manufacturers and warehousemen during September, 1959, to assure the production of clean, wholesome products, these firms reported to Food and Drug Administration inspectors. In an additional 102 voluntary actions to protect consumers, food firms destroyed or converted to nonfood uses 233 tons of unfit foods.

A California frozen-pie company spent $5,000 to prevent possible bacterial contamination of its product. The firm bought two portable sanitary pumps to transfer materials—formerly handled with buckets—and improved its freezing method to cut down the incubation period for possible bacterial growth.

A Michigan bakery supplier avoided possible insect and rodent contamination of warehoused products by storing them on newly acquired pallets for handling by fork lift and by installing new floor covering. He spent $5,484.66.

A Colorado candy manufacturer shut down his plant for one week for a complete cleanup and repainting. This was at a cost of $7,234.

Practically all the dollar value of substandard drugs voluntarily destroyed by drug firms was in a single action by a California manufacturer. Destruction was of a wetting solution to be used with contact lenses. When the manufacturer found that his product was not sterile, he voluntarily recalled from the market and destroyed stocks which were valued at $167,000.

Federal Narcotic-Law-Enforcement Policy in Relation to Drug Addiction

By ALFRED L. TENNYSON

The Writer, Chief Counsel, United States Bureau of Narcotics, Delivered This Speech Before the Division of Food, Drug and Cosmetic Law of the Amercian Bar Association, at Miami Beach on August 24

THE BUREAU OF NARCOTICS is engaged in the enforcement of the federal narcotic and marijuana laws, and related statutes involving the investigation, detection and prevention of the illicit traffic in narcotics. In the legitimate trade, the bureau supervises the import, export, manufacture and distribution of narcotic drugs for medical and scientific purposes and seeks to prevent diversions to illicit and abusive channels. Efforts are directed toward eliminating the major sources of illicit narcotic supplies by concentrating the resources of the bureau's specially trained officers on the highly organized gangs operating at the interstate and international levels and on important cases of intrastate illicit distribution. To eliminate these illicit traffickers and organizations, it is frequently necessary to develop broad and complex conspiracy cases involving all facets of the illicit narcotic traffic. Operating at these levels, fewer cases are made, but extensive efforts must be applied over longer periods of time to develop and bring these cases to trial. This approach is showing the desired results by the importance of the violators arrested and convicted.

As an example, one of our extensive investigations resulted, on July 7, 1958, in the return of an indictment by a federal grand jury in New York City naming 37 defendants in a gigantic conspiracy to violate the federal narcotic laws. The conspiracy, begun in 1954, involved smuggling of heroin in kilogram lots from Europe to New York

City, and subsequent distribution in kilogram quantities to large cities, from New York City to Los Angeles. This group is believed to have handled at least 100 kilograms of heroin. Among those arrested in this case were such important figures as Salvatore Santora; Vito Genovese, reputed leader of the Mafia; Benjamin Levine; Joseph DiPalermo; and Vincent Gigante. Fifteen of these defendants were convicted on April 17, 1959; Santora was sentenced to imprisonment for 20 years; Genovese and DiPalermo, each to 15 years and a $20,000 fine; and the other 12 received sentences somewhat less severe but still drastic, for their criminal participation.

Handling of "Unlawful Possession" Cases

It follows that state and municipal officers, and not federal officers, handle that class of narcotic cases known as the "unlawful possession" type, frequently involving drug addicts who may be prosecuted or committed under applicable state law. However, an officer of the bureau will investigate and seek to eliminate an important illicit peddler, even though the latter happens to be a drug addict. Thus, in the case of one individual whose name is withheld because of pending prosecution, it was determined that he was the source of supply of illicit narcotics in a certain area in a southern state, operating from a large house trailer which he owned. He also owned, free of any lien, a 1958 Buick automobile and a 1951 Cadillac automobile, in which he sometimes made deliveries of the drug. This man made several sales of Dolophine (a synthetic narcotic) to a special employee of the bureau; the first sale was of three tablets for $3, followed by four sales of 73, 90, 90 and 82 tablets, respectively, for $50 in each case; when arrested, he had 41 tablets of one-half grain morphine sulfate and 139 tablets of Dolophine (10mg.) in his possession. There was also in his possession over $5,500 in cash. This man was a drug addict, having been addicted, according to his statement, for 15 years. He allegedly obtained his supply of drugs from one or more doctors. The defendant had received a six-month sentence for auto theft in 1930, and a five-year sentence in 1939 for grand larcency. He had no apparent source of income other than that from his illicit narcotic activities. There is certainly no reason for giving consideration, by way of leniency, to this drug peddler.

A joint American Bar Association-American Medical Association committee on narcotic drugs was established pursuant to an American Bar Association resolution adopted in 1955 for the purpose of ex-

ploring the possibilities of "a jointly conducted study of the narcotic drug traffic and related problems." This committee, which was composed of three representatives of each association, rendered an interim report in 1958 and a final report this year. From these reports, the joint committee appears not to have studied the broad scope of the "narcotic drug traffic," such as illicit production, smuggling, illicit interstate and intrastate distribution, etc., but to have explored only the phase of supplying narcotics to drug addicts by physicians. While admitting that "zealous law-enforcement efforts have unquestionably played a part in reducing drug addition—and will undisputedly continue to be required in curbing the illicit drug traffic," the joint committee is dissatisfied with the laws and enforcement policies urged by the United States Narcotics Bureau, and recommends additional research by the two parent associations in five major areas. These areas are summarized as (1) an experimental facility for the out-patient treatment of drug addicts, (2) an extensive study of relapse and causative factors in drug addiction, (3) the development of sound and authoritative techniques and programs for the prevention of drug addiction, (4) a critical evaluation of present legislation on narcotic drugs and drug addiction and (5) a study and analysis of the administration of present narcotic laws.

It is assumed that the American Bar Association has not yet acted upon the final report of the joint committee, but it is reported in the *Journal of American Medical Association* of June 27, 1959, that the House of Delegates of the American Medical Association congratulated the joint committee on its work and urged continued study under "separate and already established councils of the A. M. A. and the A. B. A." In taking this action, it is clear that the AMA house of delegates did not give formal approval to a plan of treating drug addicts by supplying a continuing regular dosage of the drug of addiction nor did it revoke its long-standing policy of opposition to the so-called "ambulatory treatment." It is regretted, however, that the House of Delegates, before urging continued study (presumably in the five areas of the joint committee report as above identified) did not carefully review some pertinent portions of the "Report on Narcotic Addiction" by its council on mental health, which report had been adopted by the house of delegates in June, 1957. It would have been helpful, also, if the particular committee, in evaluating the report of the joint committee prior to presenting it to the house of delegates, had carefully studied the records of hearings and reports of two

Congressional committees which had made a thorough nation-wide investigation of the narcotic problem in 1955. These documents reflect the considered opinions of unbiased authoritative bodies upon a number of matters which troubled the joint committee, but these opinions apparently were not acceptable to that committee.

Outpatient Treatment of Addicts

As previously indicated, the first research project recommended by the joint committee is "an experimental facility for the out-patient treatment of drug addicts, to explore the possibilities of dealing with at least some types of addicted persons in the community rather than in institutions." Even if limited to curative treatment, this proposal would envisage nothing more than another try at the reductive ambulatory treatment, where the addict is under no restraint and may seek and obtain supplemental sources of supply from others besides the "treating" doctor or clinic; this method has been subject to long-standing condemnations by the American Medical Association and, more recently, by the Committee on Drug Addiction and Narcotics of the National Research Council, neither of which condemnations has been rescinded. But in Appendix A to the joint committee's interim report, it is stated that the AMA's council on mental health *suggested* that such a limited experiment be devised. On page 46 of the printed report of the council on mental health, it is stated that the council *gave some consideration to the possibility* of devising a limited experiment of this nature and, continues:

> Such an experiment might seem the logical way to settle the matter. There are ethical objections to such an experiment. Also, such an experiment could not be carried out within the framework of existing laws and regulations. In addition, the Council feels the problem is very complex and that it would be difficult to design a valid experiment which was limited in extent. On the other hand, a full scale trial of the clinic system for a number of years in the entire country would carry a possible risk of increasing the addiction problem.

It seems, therefore, that the AMA's house of delegates or its board of trustees has referred to its council on mental health for pertinent research and study one project recommended by the joint committee that the council has already carefully studied and on which it has submitted its definitive report which was approved by the AMA's house of delegates about two years ago.

This recommendation for an experimental project has broader significance than has a proposal for another trial of the discredited ambulatory treatment, as the context of the proposal in both reports

indicates that this will be a steppingstone to achievement of a plan to ration narcotic drugs to addicts. The final report disclaims advocacy of indiscriminate distribution of narcotic drugs; urges discouragement of such drugs except for legitimate medical needs (*sic*); urges that addicted individuals be given the benefit of all procedures to encourage them to withdraw from dependence on narcotic drugs *voluntarily*; and urges psychiatric and social-agency help for those who have withdrawn, to assure against relapse. But the report immediately states that more information is needed about the best means of handling addicts who, despite the best professional efforts, continue to be dependent on drugs. It speaks of the allegedly high rate of relapse on the part of addicts who have been in the care of narcotic hospitals, and suggests that compulsory hospitalization of all addicts is not practicable at the present time. It may be reasonably inferred that the joint committee has no greater hope than that of the council on mental health for the successful operation of the experimental facility for the outpatient treatment of drug addicts, and that the joint committee believes that "many coming to the clinic will need to be supplied with drugs and will be unable to function without drugs," necessitating the clinic's making a determination of the best means of supplying drugs to such persons. The bureau submits that this plan is simply that of rationing narcotics to addicts to maintain and increase addiction, since addiction spreads by association; that such plan is contrary to national and international principles of control; that it is opposed by the better-informed medical opinion on the subject; and that it would represent an abject surrender to a serious evil that has not been characteristic either of the Government of the United States or of the medical profession in the United States.

Dr. Leonard A. Scheele, formerly Surgeon General of the Public Health Service, has stated:

> Treatment of drug addiction must take place in a drug-free environment, in an institution with special facilities for gradual withdrawal of the addicting drug . . . . Our experience leads us to believe that the vast majority of addicts cannot be withdrawn from narcotics with hope for success without institutional treatment.

Drs. Vogel, Isbell and Chapman, experts with unique experience in treatment of addicts at the Lexington Hospital, similarly expressed the opinion: "Withdrawal of drugs from narcotic addicts on an outpatient or office basis should not be undertaken; it almost surely will fail." In September, 1955, several of the Public Health Service ex-

perts, including Dr. Felix, a signer of the joint committee report, who had supervised the treatment of hundreds of drug addicts at the Lexington and Fort Worth hospitals, testified before the Daniel subcommittee of the Senate, in effect, that they would not administer narcotics for the maintenance of addiction to an individual under any other circumstances except that of a painful illness for which there was no other relief; two of the experts did say that there might be a rare case (perhaps one or two out of hundreds of addicts) where the person had a kind of debilitating psychiatric illness and therefore might conceivably, for periods of time during the course of the illness, be supported for short periods on drugs.

The record of the Senate subcommittee hearings in 1955 shows that ample opportunity was given, for the full expression of views and arguments, to opponents of the current policy of enforcement of the federal narcotic laws; these included the chairman of the joint committee, who argued at length that it was not unethical, as far as the medical profession goes, for a doctor to dispense narcotics to an addict in quantity sufficient to keep him comfortable. The Senate subcommittee, after full inquiry into all phases of the matter, rendered its report that it was unalterably opposed to, and rejected the "clinic" plan proposal for, the supplying of narcotic addicts with free or low-cost narcotic drugs; that it was opposed to all types of so-called ambulatory treatment; and that it believed the thought of permanently maintaining drug addiction with "sustaining" doses of narcotic drugs to the addict to be utterly repugnant to the moral principles inherent in our laws and the character of our people.

Relapse and Causative Factors in Addiction

The second research project recommended in the joint committee report is "an extensive study of relapse and causative factors in drug addiction." This proposal does not represent a new object of inquiry; causative factors have been dealt with in reports from the Lexington hospital—for example, "Present Status of Narcotic Addiction," by Drs. Vogel, Isbell and Chapman.[1] Outpatient clinics *for postinstitutional treatment* have been recommended by the Public Health Service as a necessary supplement to the treatment at Lexington, and this principle has been one of the important recommendations of the council on mental health. Unfortunately, these clinics have not been estab-

[1] 138 *Journal of American Medical Association* 1019 (December 4, 1948).

lished to any great extent in communities where they are needed. The operation of such clinics should afford additional information on relapse factors and—perhaps of more immediate importance—might result to a gratifying extent in avoidance of recidivism.

Educational Measures as Preventive

The third project is "the development of sound and authoritative techniques and programs for the prevention of drug addiction." This, no doubt, refers to educational measures for the prevention of drug addiction. The Federal Bureau of Narcotics has not objected to education as a means of preventing, or helping to prevent, the formation of drug addiction; it has questioned the mass presentation of this subject to the very young and has suggested that the study be included in over-all lectures on hygiene. The policy of the Federal Bureau of Narcotics is identical with that in Canada, as expressed in the report of a special committee, composed of 23 senators, on the traffic in narcotic drugs in Canada:

> The Committee considered the question of education against the use of narcotic drugs and is of the opinion that while educational programs may usefully be established for professional groups, for parent-teacher associations, and for adult groups generally, such programs should not be used where they would arouse undue curiosity on the part of impressionable persons or those of tender years. The Committee's view is supported by the Narcotic Committee of the United Nations who recommend against any such educational program. Lecture material especially prepared by the Division of Narcotic Control and containing information respecting the economic and social factors of drug addiction has been presented regularly to Medical and Pharmaceutical Associations, Schools of Nursing, and undergraduate societies in colleges of Medicine, Pharmacy, and Nursing. This form of education should be continued.
>
> The Committee recommends the improvement and expansion of mental health programs in our schools in the hope that variations from acceptable behavior may be detected and treated before the opportunity for addiction to drugs has been presented.

Evaluation of Legislation and Administration

The fourth and fifth research projects proposed by the joint committee are interrelative and may be considered together. They are (1) a critical evaluation of present legislation on narcotic drugs and drug addiction and (2) a study and analysis of the administration of present narcotic laws. From the general tenor of the interim and final reports, it is assumed that the joint committee intends the evaluation and study to be limited to the federal narcotic laws, and federal administration thereof, and to that phase only of the federal narcotic laws

and administration that prevents the prescribing and dispensing of narcotics to drug addicts merely for the purpose of gratifying addiction. It is understood that the reports do not challenge or question the administration of the narcotic laws respecting the prevention of smuggling, illicit interstate distribution, etc.

It is significant that the chairman of the joint committee had foreshadowed his recommendations by an article—which he stated was not dispassionate—published in the *Yale Law Journal* in 1953.[2] In this article he indicated rather sweeping dissatisfaction with the manner in which the previously established narcotics division went about enforcing the so-called Harrison Act; under a subheading, "The Narcotization of the High Court," he was critical of the majority opinions of the United States Supreme Court in the *Webb*[3] and *Jin Fuey Moy*[4] cases, alleging that the tardy but corrected interpretation of the *Linder* case[5] has not deterred the Federal Narcotics Bureau in its own lusty applications of the act. He predicated that sooner or later some responsible appraiser, probably Congress, would have to take a clear look at our narcotics problem and the plight of the addict.

Congressional Investigation

Some two years later, as previously indicated herein, two Congressional subcommittees (the Daniel Subcommittee of the Senate Judiciary Committee and the Boggs Subcommittee of the House Ways and Means Committee) did make a nation-wide investigation into narcotic law enforcement, holding extensive independent hearings on the subject. The chairman of the joint committee appeared before, and expressed his views to, both of these subcommittees; before the Daniel subcommittee he discussed the Supreme Court narcotic decisions and the administrative regulation in much the same manner as in the *Yale Law Journal* article; in reply to the question whether he felt that Congress should amend the law so as to provide that doctors can give drugs to addicts for the purpose of making them comfortable by maintaining their customary use, he said "yes." We may be sure that both Congressional subcommittees carefully evaluated the federal narcotic laws as administered, but they did not agree with the chairman of the joint committee relative to an amendment to allow doctors to furnish narcotics to addicts to make them comfortable by maintain-

[2] 62 *Yale Law Journal* 736 (1953).
[3] *Webb and Goldman v. U. S.*, 249 U. S. 96 (1919).
[4] *Jin Fuey Moy v. U. S.*, 254 U. S. 189 (1920).
[5] *Linder v. U. S.*, 268 U. S. 5 (1925).

ing their customary use. Both subcommittees disapproved of this principle, but recommended legislation which was enacted as the Narcotic Control Act of 1956,[6] providing for (1) greater penalties for unlawful sale of narcotics and (2) certain other enforcement facilities.

The joint committee's chairman and its director of narcotics control study, in making their respective studies of the so-called Harrison Act and its interpretation by the courts, have urged, in effect, that the *Linder* case overruled the *Webb* and *Jin Fuey Moy* cases. In the *Linder* case, the indictment did not specifically challenge the good faith of the physician or negate the fact that the sale was in the course of professional practice only, as did the indictment in the previous *Jin Fuey Moy* case. In the course of the Supreme Court's decision, there was discussion that direct control of medical practice in the states is beyond the power of the federal government; the court had, however, first significantly noted that the indictment "does not question the doctor's good faith nor the wisdom or propriety of his action according to medical standards" and that "it does not allege that he dispensed the drugs otherwise than to a patient in the course of his professional practice or for other than medical purposes." All that the *Linder* case really holds, therefore, is that, in the absence of an allegation in the indictment negativing good faith and professional practice, the Court cannot supply the omission by holding as a matter of law that the sale of four tablets of narcotics necessarily transcends the limits of professional practice. In at least ten cases,[7] decided by five different United States Courts of Appeals throughout the years *since* the *Linder* case was decided (1925), the courts have affirmed judgments of conviction of physicians for making unlawful sales of narcotics where the indictments (unlike that used in the *Linder* case) duly negatived "good faith" and "in the course of professional practice only."

Bureau Position on Committee Proposals

The bureau of narcotics does not oppose objective research in the field of narcotic drugs. It does not approve the establishment of an outpatient clinic which would dispense narcotics to addicts, even as a "limited experiment," for much the same reasons that the council on

[6] 70 Stat. 567.

[7] *Bush v. U. S.*, 16 F. 2d 709 (CA-5, 1927); *Boehm v. U. S.*, 21 F. 2d 283 (CA-8, 1927); *Nelms v. U. S.*, 22 F. 2d 79 (CA-9, 1927); *Freeman v. U. S.*, 86 F. 2d 243 (CA-5, 1936); *Ratigan v. U. S.*, 88 F. 2d 919 (CA-9, 1937); *Hawkins v. U. S.*, 90 F. 2d 551 (CA-5, 1937); *U. S. v. Lindenfeld*, 142 F. 2d 829 (CA-2, 1944); *U. S. v. Abdallah*, 149 F. 2d 219 (CA-2, 1945); *U. S. v. Brandenburg*, 155 F. 2d 110 (CA-3, 1946); *McBride v. U. S.*, 225 F. 2d 249 (CA-5, 1955).

mental health disapproved this proposal. As to a critical evaluation of present narcotic legislation and a study and analysis of the administration of present narcotic laws, both of these proposals seem already to have been implemented, first, by the chairman and the director of narcotic drugs control study of the joint committee, who reported in opposition to the present system and, second, by the two Congressional subcommittees which did not agree with the conclusions of the representatives of the joint committee, but arranged for supplementary legislation to strengthen the existing system.

The imposition of heavy penalties for illicit narcotic peddling—particularly those penalties authorized by the Narcotic Control Act of 1956—continues to be an important factor in reducing the availability of these drugs for improper purposes, and it results in the decrease of the drug-addict population. Even the final report of the joint committee admits that "zealous law-enforcement efforts have unquestionably played a part in reducing drug addiction." There can be no justification for considering the enactment of laws—federal and state—to permit government-operated service clinics or other agencies to sell or distribute narcotics to gratify, perpetuate and increase drug addiction in the United States. **[The End]**

• FDA REPORTS ON RADIOACTIVITY IN VEGETABLES •

The United States Food and Drug Administration reported on October 14 that amounts of radioactivity being found in fresh vegetables are well within the safe limits recommended by the National Committee on Radiation Protection and Measurements. In its second report of a continuing series, the Food and Drug Administration covered 402 samples of fresh vegetables collected in the latter half of 1958 and 139 samples collected so far during 1959. Vegetables included cabbage, cauliflower, celery, beans, broccoli, Brussels sprouts, collards, beet tops, lettuce, kale, mustard greens, parsley, potatoes, tomatoes, peppers, spinach, turnip greens and water cress.

The highest average total beta radioactivity found for any vegetable so far examined was 6,700 micromicrocuries per kilogram for spinach. The average for all vegetables from all sources was 2,520 micromicrocuries per kilogram. The highest single value was 56,000 micromicrocuries per kilogram obtained on a sample of spinach from Illinois.

A curie is the amount of radiation given off by one gram of radium. A micromicrocurie is 1 millionth of a millionth of a curie.

As a part of a cooperative Food and Drug Administration-Atomic Energy Commission arrangement, samples of certain United States staple foods are furnished by FDA to the Lamont Geological Observatory for strontium-90 analysis.

Food Packaging

AND THE 1958 FOOD-ADDITIVES AMENDMENT

By CHARLES W. KAUFMAN

The President of the Packaging Institute—Addressing the 1959 ABA Meeting in Miami Beach—Noted That Government Officials Must Give the Packaging Industry the Time "So Necessary to Accomplish . . . Compliance with a Good Law That Will Best Protect the Health of the Consuming Public"

IN THE PROCESS of bringing foods from farms and fields to cities and towns and to the customer's favorite store and ultimately to the customer's table, there must be provided a means of combating the various ravages of many chemical, microbiological, climatic and physical abuses that are at work to render food either useless or, at least, unappetizing. A chemical, oxygen, for instance, can cause bleaching or darkening of a food and usually it causes early rancidity in most fatty foods. Oxygen causes many queer or strange off flavors to develop unless some control is exercised over the food product. Mold and bacteria are microbiological pests except in very special cases that can (besides making food unpalatable or appealing) make it harmful unless controlled. Absorption of moisture by crackers and loss of moisture by bread are climatic effects that must be guarded against by the manufacturer if today's consumer is to be satisfied. Broken eggs, crushed cake, pinched tomatoes or crumbled cookies are the result of the mechanical or physical hazards that our foods are exposed to on their way from their source to the home.

To combat these destructive forces is the prime function of the food package. The secondary function of a food package is to provide a measure of convenience, such as easy storage or means of carrying, and a means of identification, such as ingredient clauses, weights or measures, and manufacturer identity. In other words, a food package is food protection, food economy and food convenience all rolled into one.

Packaging Progress

While doing such a necessary and magnificent job, a packaging industry has developed and utilized the metals, glass, plastics, paper, wood and cloth of industry. The total packaging industry is estimated to be over a $15 billion industry—a giant of American enterprise. Using these commodities singly and in combination, together with adhesives, waxes, specialized varnishes, lacquers and inks, the United States has been given a higher standard of eating than any other nation in the world. The food packagers have made gourmets of all of us as we select plain or fancy foods, either in or out of season, from all parts of the world, any time we step into American stores. From the beginning of time man has sought to package better and better, but I believe we all can recognize that the real food-packaging revolution is probably not over 30 years old and is still going strong.

Many of us will think of packaging progress only in terms of the step that was taken when we went from the cracker barrel, which the grocer's cat usually protected by sleeping on the cover, to the cracker box or to the subpackage or to the individual wrap served in restaurants. We might think of progress being that packaging that brought us from the wheel of cheese on the counter to the sandwich-size slices, or from beer in barrels to bottles and cans. There is so much to think about in food packaging when you consider the hundreds of items that are available to us in our market place that we take for granted the job that packaging is doing for our food industry. The food package is a real benefactor of the consumer in that sanitation is of paramount interest to this industry, as is the control of weights and measures, which packaging makes possible. Dinners that are ready to heat and serve in a hurry and cream that whips itself as it comes from the package are only forerunners of the conveniences in foods soon to be seen.

Contribution to Health and Welfare of Nation

A tremendous amount of science, technology and ingenuity has been poured into our job of making this Nation the best fed on earth. But, as Thomas Fuller once said: "A good example is the best sermon." Thus, I believe that the state of our Nation's health and welfare is the best evidence of the successful job food packaging is doing today.

I suppose it might be said that we did not arrive at our present stage of progress in food packaging and distribution always by means

of pure scientific data, and to this I must agree. Certain risks or judgments were undoubtedly taken which were either demonstrated successfully or quickly abandoned. Consider, for example, that wax had commonly been used in early times to provide moisture barriers for foods such as cheese, meats and homemade jellies; it has now become a component part of the coating for paper to be used as bread wraps, milk cartons, frozen food cartons, cereal wraps, butter wraps, candy wraps, and so on and on and on. If the history of waxes were to be traced, you would find that the risks taken by using it as a food-packaging material were justified. The same thing would be true with coatings on cans for food, plastics as containers, construction materials and transportation systems, and sometimes a little "risk" might be justified in law. All in all, I think that all should agree that food packaging in this country is something to be mighty proud of and something to be protected as necessary to our national health.

Toxicology—Urgent, Serious Problem

Obviously, no one can, or even wants to, stop this progressive and dynamic thing called "food packaging"; the benefits are obviously too great and necessary. But today the food-packaging industry is faced with solving quickly a serious problem not altogether new, but in its urgency "new." This problem is, simply stated, toxicology.

The food industry itself has always had this problem to deal with, but to the packaging field it is a relatively new concept as defined under the new food-additives amendment, which requires proof, before it can be used, that the package for food is nontoxic. Even a purposely simplified discussion of the problems facing the packaging industry will demonstrate the problems that face us.

Most of us who are working with these problems of package toxicity are finding that many of the problems now created are more complicated than those of food additives themselves and, Heaven knows, they are complicated. We need not question the need for regulations and controls over foods and packages for foods, and everyone, I'm sure, has felt or considered the need at some time or another for new guideposts and assurances for the safety of the diet of our people. We know that the old "per se" clause in the food and drug Act, as an example, was not too well thought of in the past by manufacturers.

In packages, toxicity becomes first a matter of the migration of a chemical from the package to the product and, as has been said before, this will vary considerably, depending on the nature of the food and its natural storage conditions. This migration may be quite selective, too, dependent upon whether the food is fatty or nonfatty; the pH of the food is another factor; whether the food is liquid or solid, frozen or nonfrozen or whether it is abrasive or not, will be important criteria as to each packaging material. After migration has been determined, we must know *what* migrates. In the case of a plastic it may be a monomer, polymer, plasticizer, antioxidant, stabilizer or a lubricant, or a combination or even a heretofore unknown reaction product of these things.

Paper Production as Example

To see how complex this problem might be, consider for a moment the most common packaging material of all—paper. Wood is digested in a chemical bath of sulfides or sulfites, to free the cellulose for use in making paper. Fungicidal treatments may then be added to prevent the build-up of slime in the piping system of the paper-mill equipment. Any one of a dozen chemicals may then be added to bleach the paper or still other chemicals may be added to impart the "whiter than white" effect, as we do with various laundry preparations. Later on are added the resins, rosins, starches, gums, waxes, rubbers, plasticizers of both natural and synthetic varieties which are the sizes that make the paper printable or receptive to the additional coatings and treatments that will impart greaseproofing, gasproofing, and moisture proofing properties to the paper. There are at least a hundred chemicals involved here which have been used and accepted for decades, conservatively speaking, almost all of which have no significant past toxicological history at this time. You can surely imagine the amount of toxicological work that is now going to be necessary in this field alone, as work is done to comply with the current amendment.

The actual basic chemistry of plastic polymers is now, as always, under vigorous study which logically should precede the feeding tests and the pathology work that lies ahead. This basic work is far from complete.

As I now think about it today, the major problems facing the food-packaging industry as a result of the present food-additives amendment which deserve our attention are those of publicity, manpower, money and time.

Effects of "Scare" Publicity

Publicity will be considered first. The current attention being given to food packaging as a result of the amendment could be—but must never be construed as—an indication that the health and welfare of the public has ever been a pawn in a wild scramble of manufacturers and marketeers in the packaging field. One who has visited the laboratories around the country knows the care exercised in food and package research. "Scare" publicity—pseudoscientific articles, half truths, misinterpretations, misquotes—are beginning to have effects and must be stopped. It is hard to say at this time how many people now believe (because of publicity in June) that milk in waxed cartons may cause cancer. Newspapers and radio and TV news all carried various interpretations of what the known facts in the case are. As a result, some milk orders were actually canceled except where milk would be furnished in glass with the paper disk cover. The same coverage or equal time was not given to the later denials coming from Washington.

Those of us who can report to the public, and are called upon to do so, would do well to create confidence in the science of government and industry with the whole truth. Let us strive not to get ourselves into the dilemma of the attorney who has something stricken from the record after the jury has heard the statement.

Problem of Adequate Trained Personnel and Specialized Testing Facilities

As above stated, manpower is a second problem facing us in this matter. The legal profession is, I believe, ready and able to handle the services required by the industries involved. The food manufacturer has a technology developed and either has qualified scientific personnel already on his staff or a source for this service is already established. But the majority of packaging converters and suppliers who undertake formulation work on coatings, adhesives, sprays and lubricants, and inks (many of which have normally and heretofore been treated as trade secrets) do not now have the caliber of trained personnel or specialized laboratory facilities to conduct the thorough toxicological studies now required. I seriously doubt that there is enough of this type of personnel available in the whole of the pulp and paper industries at this time even to begin to cope with the many questions on a sound scientific basis. There is a definite shortage

of toxicologists and pathologists in industry's laboratories, and the mere handful of consulting laboratories could not handle the matters before us without much additional manpower and time.

Where will these qualified scientists come from by 1960, 1961 or 1962? This problem is far from being resolved.

High Costs Prohibitive to Developments by Smaller Businesses

Referring briefly to the question of money, it may be stated that the costs of the type of investigations needed today for a chemical which we now know will range from $50,000 to $500,000 and upward. These new costs of obtaining assurance of safety needed for packaging will be reflected in research budgets and, eventually, in sales costs to the customer. It might suffice to say that budgets may tell us what we can't afford, but do not prevent us from buying. Actually, it appears that new developments by smaller businesses will not only be seriously handicapped, but their introduction may be eliminated by the high costs involved in getting products toxocologically cleared before they can be offered for sale.

There are, however, a number of tricky little situations that are going to arise—for example, the case of a compound used in confections as a desirable strawberry flavor adjunct (cyclohexyl butyrate). I understand that about eight to ten parts per million of this chemical are used in a product, and it is worth somewhere between $4 and $5 a pound. The total annual production of a so-called "food grade" of the material is probably not more than 1,000 pounds. Thus, for $4 or $5 worth of product per year, how much can the manufacturer pay to have the required toxicology work performed?

Seneca, the philosopher, said that "nothing is ours except time," and time is another problem. The current timetable set forth by the amendment now can hardly be expected to be met unless compromises, arbitrations and extensions are obtained. It is generally felt, I believe, that if the food-packaging industry had known in September, 1958, what the problems were—what to test, what to feed, **what to study**—even then the job could not be completed by March, 1960.

I know that the problems facing this industry will be solved and there is no doubt about it. But the amount of research, time, money and manpower required for this job is not now known. We

all have a responsibility to look for answers for American industry in these matters.

The progress this industry has made in the past 15 or 30 years is indicative of the ability and energy that will be put into the task of getting answers. I can assure you that the packaging industry and its supporting industries are doing something. The associations of the various trades involved are holding meetings like ours today, trying to develop both questions and answers to the major problems we face.

Some trade associations which are well financed have engaged both legal and scientific counsel or have sponsored joint research programs or have provided for educational grants in colleges and universities to study their problems. Some major firms are privately working with FDA and are giving as much effort as possible to the early solutions of their problems. Admittedly, there are some who, with Alexander Dumas, believe: "All human wisdom is summed up in two words: wait and hope." But the progressive packaging industries are not included among these. The food manufacturer has little it can do except wait and hope. It can ask of its supplier only approved supplies which may or may not be forthcoming. If the approval is given, all is well; if not, alternatives for packaging are needed. What will they be? Will new machinery be needed? Will new costs be added?

One supplier has already told our firm that his current packaging material will not be supplied after March, 1960. He will not get it cleared. He will try to arrange for a substitute, but no assurances are given. The new material may not develop. It may not work in production, and time is fast running out. What is the alternative? The answer is obvious: time.

Matters to Be Referred to "Experts"

A final problem is as to matters that will be referred to "experts" for their opinions. The expert will not render an opinion in the absence of scientific data, of course, but in the field of toxicity of packaging materials there will undoubtedly be many times when the toxicity will be resolved by a matter of degree. Ordinary table salt is a chemical used as an additive to food and is both good and bad, depending upon degree. The early Roman Empire paid its soldiers

with salt, from which we get the word "salary." These same Romans put excessive salt in their prisoners' food as a punishment for their crimes. Whether salt is good or bad is a question of degree, as with most things we eat or drink.

Oxalic acid "per se" is a dangerous poison, yet for years the philosophy has been accepted that spinach is "good for us." Look what it does for Popeye! Spinach, as Nature grows it, contains a *small* amount of oxalic acid. This factor of quantity must be given consideration; under the new measure such consideration is permissible—making it a measure superior to the old law of "per se."

Many other foods—common foods—contain traces of compounds which, by themselves, are known to be injurious to human health, but again it's a matter of degree. An unrestricted diet of pills purchased in any drugstore could be dangerous—another matter of degree. Obviously, drugs and medicines are different and no one expects the consumer to ignore the label or instructions and make a meal out of medicine. Likewise, no one expects a consumer to make a meal out of bicarbonate of soda—a harmless material, to a degree—or salt or vinegar. The effects that packages may have on foods should also be subjected to these same considerations of degree.

In conclusion, it should be considered that so far it has taken ten years to develop the food-additives amendment through committees, hearings and Congress, and one year to crystallize the legal and scientific problem involved in applying the food-additives amendment to the packaging industry. Some of these problems have been solved by the language of the law, but many more need the cooperative efforts of lawyers, scientists, public officials, and industry representatives before satisfactory solutions are reached. Solutions to the problems which we face require manpower, money and time. Let us remember, then, the importance, to our Nation, of the food package; let us recognize the magnitude of the task that lies ahead; and let us look to the regulative and administrative officials to give not only direction and guidance, but also the time that is so necessary to accomplish our mutual purpose of compliance with a good law that will best protect the health of the consuming public. In the interests of this consuming public, it is not too soon for our elected officials, our regulatory agencies and the members of the bar to recognize that more time must be provided—either by regulation or by Congressional action—to permit industry to do the job at hand. **[The End]**

Proposed Color-Additive Amendments to the Federal Food, Drug, and Cosmetic Act

By FULLER HOLLOWAY

The Writer, Counsel for The Toilet Goods Association, of Washington, D. C., Notes: Science Is Advancing Too Rapidly to Be Restricted by Statutory Boiler Plate. He Addressed the Recent ABA Meeting in Miami Beach

LEGISLATION with respect to colors has been a matter of considerable discussion, at least since 1953, when the Food and Drug Administration published its notice in the *Feder ' Register* proposing to delist FD&C Red No. 32, FD&C Orange No. 1 and FD&C Orange No. 2. The Department of Health, Education, and Welfare released its preliminary draft of a color-additives bill on April 10, 1959. There had been bills relating to colors introduced in Congress previously.

During the hearing in January, 1954, with respect to the delisting proceedings to which I have previously referred, Dr. Vos, a pharmacologist of the Food and Drug Administration, was questioned with respect to the harmlessness of common salt. On reading the definition of color additive in the preliminary draft of the Executive Department, I recalled that 1954 hearing and thought: "They have now made salt a color additive."

Industry was afforded an opportunity by the Food and Drug Administration to discuss this preliminary draft. Representing the Toilet Goods Association, Mr. S. L. Mayham, the executive vice president, and I, as counsel, suggested that the draft be changed in three respects: (1) the definition of the term "color additive," (2) the provision in the proposed Section 706(b)(4) with respect to the mandatory

requirement that the Secretary shall not list a color additive unless the data before him establishes that practicable methods exist for determining the identity and quantity of any substance formed in or on any article of food, drug or cosmetic because of the use of such additive and (3) the provisions of Section 203 of Title II, relating to effective dates and transitional provisions, as such section provided an arbitrary closing date for provisional listing of colors.

Major Questions

First, we were troubled by the definition of "color additives" because it seemed to us that the definition in the preliminary draft could be interpreted to include a finished cosmetic itself as a color additive. The definition was changed and the bills as introduced—S. 2197, by Senator Hill, and H. R. 7624, by Representative Harris—would appear to be satisfactory in that respect.

Our second major question was not resolved in the bills as introduced in the Senate and in the House; however, it is believed that a satisfactory solution is contained in language, agreed to between the Administration and industry, which it is hoped will be substituted for the language under the proposed amendment to Section 706(b)(4) of the bills as introduced. The recommended change would delete subparagraphs (B) and (C) from Section 706(b)(4) and revise subsection 706(b)(5) to read:

(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors . . .

(D) The availability of any needed practical methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive.

The third major problem, to which I have referred as contained in the preliminary draft, has been the subject of change in the bills as introduced. Thus, Section 203(a)(2) provides that:

(2) For the purpose of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date, or (B) with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph.

Thus, in the event that investigations as to safety of a color additive are not completed within the period provided, the Secretary may

extend such period for carrying to completion the scientific investigations necessary for making a determination as to listing a particular color additive.

It would seem that the greatest problem with which the Food and Drug Administration has been faced under existing law is that of "accumulations." Such problem lurks throughout the debate flowing through the administrative hearings and into the decisions of the courts with respect to the delisting of colors. The problem of accumulations is intimately connected with the establishment of tolerances in the use of color additives. The pending bills, providing for a new Section 706 of the Federal Food, Drug, and Cosmetic Act, look toward the solution of the accumulations problem and the establishment of tolerances by stating under paragraph (4) of subsection (b) of Section 706 the paramount consideration of safety under the specified conditions of use. Under paragraph (5) the considerations of accumulations are taken into account and under paragraph (7) the rules with respect to tolerance limitations. Under paragraph (8) of Section 706(b), as a necessary refinement to the accumulation problem, the Secretary can under the stated criteria allocate, when necessary for purposes of safety, the aggregate allowable safe tolerances among the uses under consideration. One may argue with the criteria for the allocation, but it would seem that very little has been resolved by this proposed legislation without the power to make allocations and set tolerances.

"Accumulations" Problem

It would seem that the new subsection 706(b)(6) requiring the Secretary not to list a color additive for a proposed use which would promote deception to the consumer has no application to cosmetic users—at least I so interpret the subsection. It is not my understanding that the Secretary has any desire for, or should have, any authoritative judgment as to esthetic values in cosmetic colors. The deception referred to is that of the consumer, who, in the case of cosmetics, deliberately buys the cosmetic for the *color* qualities displayed. In short, she buys that cosmetic for that color. I do not believe that the provision is intended to deprive any lady of her fundamental privilege to promote a little deception of the male by the use of colors to make him believe that she is more beautiful than she otherwise may appear.

The bill as introduced in the Senate (S. 2197), although otherwise identical, does not contain a clause specifically relating to a single ailment—cancer—as does the bill introduced in the House (H. R. 7624), in subparagraph 706(b)(5)(B). Paragraph 706(b)(4) of both bills very clearly directs that the Secretary shall not list any color additive for any proposed use unless the data before him established that such use will be safe.

Two or three years ago it was my good fortune to be present at a luncheon at the Press Club in Washington, at which the great heart specialist, Dr. Paul Dudley White, was the principal speaker. During the course of his talk, Dr. White touched lightly on the subject of alcoholic beverages in relation to the heart and, to the best of my recollection, suggested that discreet use of alcoholic beverages could well be beneficial in relaxing a tense person. As is the custom at the Press Club, at the conclusion of his highly enjoyable and enlightening discourse, various reporters sent to the rostrum written questions directed to Dr. White. One reporter queried: "Do you believe that it would be all right, doctor, if one took an occasional drink throughout the day?" Dr. White answered that one might as well expire by reason of heart trouble as by cirrhosis of the liver.

Department's Need to Be Allowed Full Use of Scientific Advancements

Science is advancing too rapidly to be restricted by statutory boiler plate. Certainly, the Department should be allowed full use of scientific advancements in making its determination of safety no matter what the condition under guard.

The proposed legislative amendments, as introduced, have had the advantage of scrutiny and discussion from all sides, which, I believe, has made for much better understanding and solutions. The matters built in for consideration and solution at the administrative level can be solved better at that level and through discussions among men dedicated to safety in foods, drugs and cosmetics, in and outside of government. **[The End]**

The Projects of Uniform Food Codes in Latin America and in Europe

By JULIUS G. ZIMMERMAN

The Writer, an Attorney, of New York City, Presented His Paper at the Annual Meeting of the Division of Food, Drug and Cosmetic Law of the American Bar Association, Held on August 24, at Miami Beach, Florida

EVERYWHERE IN THE WORLD, and particularly in the Western Hemisphere and in Europe, great efforts are being made by governments, by international governmental and nongovernmental organizations and by national associations of the various professions and industries concerned, to modernize existing laws, regulations, standards and practices relating to the manufacture and distribution of food in order to bring them in line with the great progress made in the field of food science and food technology during the past two decades. As science and technology are universal disciplines and trade and commerce have the natural tendency to cross national boundaries wherever they are permitted to do so, the end of World War II and the resumption of international relations on a world-wide scale engendered a new era of close international cooperation in the field of food science, food technology and food legislation. The great and difficult task of making an inventory and a comparative study of the food laws of the various countries has been undertaken and is being conducted relentlessly by various organizations and research institutions. The compilation alone of all such laws and regulations seems to be an unending task and must be implemented by translation into the most important world languages so that the material can be properly studied and evaluated by all concerned.

It is common knowledge that a great diversity of food laws and food standards still exists in the majority of the countries of the world

and that such diversity is one of the most serious impediments to the development of international trade in food products. This is especially true in Europe where a great movement is under way to create wider consumer markets by the establishment of customs unions or free trade areas composed of a number of individual countries. In due course, customs controls are to be reduced or eliminated in order to facilitate the free flow of goods within the areas whereas a diversity of food and labeling laws of the member countries and any attempt to enforce them would have the opposite effect. This important economic factor should not be overlooked at the occasion of a survey of the trends toward uniform food legislation.

On the other hand, governments, scientists, manufacturers and consumers of food are equally concerned with the public-health aspects of the food that is being produced or sold in their respective countries and with the protection of consumers against economic frauds in connection with the sale of this basic commodity. For that reason, a movement toward unification of food standards and the drafting of uniform model food codes which could eventually be adopted on a regional or international scale was a perfectly logical and necessary sequence.

But it is a long way from conceiving an idea or starting a movement to the accomplishment of the desired result. The mere drafting of a comprehensive food code is a monumental task, but to draft it in such a way that it becomes acceptable to more than one country requires unusual skill of draftsmanship based on sound technical knowledge and an understanding of the practical problems with which the food industry and the law-enforcing departments of the governments are confronted. At present only two major attempts are being made to draft and to promulgate uniform model food codes on an international scale—one in Latin America and one in Europe.

Latin-American Food Code

The drafting committee of the Latin-American Food Code, under the chairmanship of the illustrious Carlos A. Grau of Argentina, can claim the distinction of having won the race in the international food code competition by preparing in less than four years a complete draft of the most comprehensive model food code the world has seen so far. The moving force behind the idea of adopting a uniform food code in Latin America was a semiofficial professional organization of Latin-American chemists which counted many government officials as its

members and which has been meeting every few years since 1924. This was also the year when a resolution proposed by Dr. Antonio Ceriotti, calling for the drafting of a *Codex Alimentarius Sudamericanus*, was adopted. The draft of such a code, consisting of 154 articles with definitions of food products and some general provisions, was submitted to the Second South-American Chemical Congress in Montevideo in 1930, but was not debated or further acted upon. The matter rested until 1955, when the Sixth Latin-American Chemical Congress held in Caracas created another and greatly broadened drafting committee which was to consist of one delegate and one deputy delegate from each of the 20 Latin-American republics and from Puerto Rico, under the chairmanship of Dr. Grau. All invited countries, except Costa Rica, Dominican Republic, Nicaragua and Paraguay, responded by appointing delegates to the drafting committee. The committee was instructed to submit—and did, in fact, submit—a complete draft of a model food code to the Seventh Latin-American Chemical Congress, in Mexico City on April 2, 1959.

The tremendous task which the committee undertook to complete was made easier by several favorable circumstances. One was that the common language of the Latin-American republics is Spanish except for Brazil (Portuguese) and Haiti (French). Another one was that all Latin-American republics are "civil law" countries and have similar systems of administrative law. The greatest asset of the committee, however, was Dr. Grau, a man of long-standing international fame as a food chemist, pharmacologist and pioneer in modern food legislation. He is the author of the elaborate *Codex Alimentarius* (also called "Bromatological Code") of the Province of Buenos Aires (promulgated in 1927)—the first such code in Latin America. This code was greatly enlarged and improved in three subsequent editions —1937, 1944 and 1949—and it served as a model for the National Bromatological Code of Argentina (the federal law) which was promulgated in 1953 and which, in turn, greatly influenced the preliminary draft of the Latin-American Food Code. This preliminary draft, with amendments, was submitted to the Seventh Latin-American Chemical Congress, which approved and recommended it as a suitable model food code for the Latin-American republics. At the same time, the congress set up a permanent Latin-American Food Code committee, likewise under the chairmanship of Dr. Grau, thus making it clear that the draft was not meant to be a final or immutable docu-

ment, but merely a starting point which was to remain subject to periodic amendments and improvements dictated by practical experience and the progress of food technology and scientific research. This permanent committee was authorized to examine and adopt recommended amendments and to submit a progress report to the Eighth Latin-American Chemical Congress, scheduled to meet in Buenos Aires in 1963.

As to the general philosophy behind the Latin-American Food Code, Dr. Grau pointed out on various occasions that it was not doctrinary but practical. In its concept, food should be wholesome but not necessarily something that is completely "natural." In this respect, the code followed an idea adopted by the Fifth Latin-American Chemical Congress in Lima in 1951, which recommended replacement of the term "pure food" with "normal food" to indicate that the presence of certain impurities or the use of harmless food additives may be permitted under certain circumstances, in line with the basically liberal policies embodied in the food law of the United States. Even while the preliminary draft of the code was in preparation, Dr. Grau made a special effort to invite constructive criticisms by government officials, professional organizations and the food industry of other countries in the Western Hemisphere, including the United States. Copies of the individual chapters were made available to the United States Department of Commerce; the Food, Drug and Cosmetic Law Section of the Inter-American Bar Association; and to The Food Law Institute. An English translation of the preliminary draft was made with the help and cooperation of various linguists, scientists and experts from government and the food industry and widely distributed in the United States. A great many comments and suggestions were received from government officials, scientists, lawyers and manufacturers which were transmitted to Dr. Grau's committee and many of which have been incorporated in the text of the code by way of supplements.

At the meeting of the Food, Drug and Cosmetic Law Section of the Inter-American Bar Association in Miami on April 14, 1959, which Dr. Grau attended as a guest of honor, he pointed out that his permanent Latin-American Food Code committee would be very happy to closely cooperate with the Food, Drug and Cosmetic Law Section to further improve the text of the food code, particularly from the point of view of legal language and terminology. He also observed

that this was the first time that a professional organization of chemists was cooperating with a professional organization of lawyers on an international level in a project of mutual interest. Dr. Grau's permanent Latin-American Food Code committee is planning to arrange for the printing and publication of the official approved Spanish version of the Latin-American Food Code which will probably include the amendments contained in the first five supplements to the preliminary draft.

In its present form, the Latin-American Food Code contains 20 chapters and 797 articles. Originally, it contained 19 chapters, but a chapter on Fishery Products was added, and some of the chapters and articles were renumbered: Chapter I, "General Provisions"; Chapter II, "General Requirements for the Manufacture and Sale of Food Products"; Chapter III, "Storage, Conservation and Treatment of Food Products"; Chapter IV, "Utensils, Receptacles, Containers, Packaging, Apparatus and Accessories"; Chapter V, "Labeling"; Chapter VI, "Meat and Meat Products"; Chapter VII, "Fishery Products"; Chapter VIII, "Fats"; Chapter IX, "Dairy Products"; Chapter X, "Cereals, Flours and Derivative Products"; Chapter XI, "Sugars and Sweets"; Chapter XII, "Vegetable Products"; Chapter XIII, "Soft Drinks and Refreshing Foodstuffs"; Chapter XIV, "Fermented Beverages"; Chapter XV, "Distilled Beverages"; Chapter XVI, "Stimulating Products (Cocoa, Coffee, Tea, Maté, Tobacco)"; Chapter XVII, "Food Additives"; Chapter XVIII, "Dietetic Products"; Chapter XIX, "Various Products (Animal Foods, etc.)"; and Chapter XX, "Articles of Domestic Use (Cosmetics, Disinfectants, Insecticides, Soap and Detergents, Toys, Industrial Products, etc.)."

It remains to be seen, of course, how soon and to what extent any of the Latin-American republics or Puerto Rico will incorporate the new model food code in their law. So far, Argentina is the only country which has a food law basically similar to the Latin-American Food Code. Chile recently promulgated an elaborate food code of its own (*Diario Oficial* No. 24,395 of July 18, 1959), which replaced the former, rather sketchy legislation on this subject, but which differs considerably from the Latin-American Food Code. Colombia, Cuba, Mexico and Peru, as well as several states in Brazil, have also been working for quite some time on their own drafts of food legislation but they now have representatives on the permanent Latin-American Food Code committee. In any case it is safe to assume that it may take

considerable time before the new model food code is actually enacted, as a whole or in part, by any of the Latin-American republics. In this final stage we may as yet see faster action in Europe with respect to the local enactment of the European Food Code because of the necessity of implementing the Common Market scheme, the Free Trade Association, and similar developments.

European Food Code

The idea of international cooperation in the field of nutrition and food law in Europe can be traced back to a chemical congress in Brussels in 1894, but it took 62 years before concrete steps were actually taken to set up a special organization with the main task of drafting a European food code *(Codex Alimentarius Europaeus)*. The political subdivisions of the European continent, the great diversity in the laws, traditions, customs and languages, and two world wars and other upheavals delayed any effective work in this field until after the end of World War II, which resulted in the creation of the United Nations and its specialized agencies, a general consolidation of the political situation and, more recently, a new era of international cooperation and economic prosperity, at least in Western Europe.

As in Latin America, one of the main driving forces behind the idea of a European Food Code is a distinguished former health official, Dr. Hans Frenzel, former Austrian Minister of Social Affairs and president of the committee for the creation of a European food code. Dr. Frenzel, who was one of the delegates attending the second symposium on food additives ("Foreign substances in food") in Amsterdam in 1956 proposed to set up a special organization just for the purpose of creating a European food code. A separate proposal to the same effect was made by Dr. León Villanúa, Professor of Bromatology at the University of Madrid. The International Commission of Agricultural Industries (CIIA) and the Permanent International Bureau of Chemistry (BIPCA), which were the sponsors of these international symposia, supported the idea and, in April, 1958, a special Codex conference was held in Paris under the auspices of the CIIA and was attended by representatives of 19 European nations and by observers from other countries, including the United States, and from various international organizations. It was decided to hold a formal conference in Vienna in June, 1958; this conference adopted a provisional charter and bylaws of a permanent organization which is to undertake and to

complete the task of drafting a Model European Food Code and which was given the name of "European Council of the *Codex Alimentarius*."

Dr. Frenzel was elected first president of the council, which was formed with the idea that it would eventually join some already-existing international organization. Until such time, however, it is to function as an autonomous entity. The council consists of three separate bodies—the conference, the board, and the two secretariats.

The conference consists of all regular member states of the organization and is formed by the official delegates of the various governments. It is the policy-making body of the council and the supreme authority in the organization. Resolutions require a two-thirds majority of votes cast. The board consists of a president, three vice presidents and the secretaries-general of the two secretariats; it is the executive body of the council. The members of the board are elected by the conference by simple majority for a period of three years (the first president, Dr. Frenzel, was elected for four years) and may not be re-elected immediately to the same office. There is a secretariat with headquarters in Paris, which is administered by the CIIA, but Dr. Frenzel also established a secretariat of his own at his domicile in Vienna.

The board has the right to invite representatives of nonmember governments and organizations to attend a meeting as observers without voting rights. The board may also appoint any members of committees, subcommittees and working groups to perform any special tasks assigned to them. The necessity for this elaborate setup, which has no counterpart in Latin America, becomes obvious when one considers the present membership of the conference which is the legislative body of the organization. There are six countries which have joined in the "common market" scheme—France, Federal Republic of Germany (West Germany), Netherlands, Belgium, Luxemburg and Italy. These countries which have already taken the first step toward a free trade area within their common borders, have a particularly urgent need for uniformity in their food standards. Then there are the four Scandinavian countries—Sweden, Norway, Finland and Denmark—which are already closely cooperating in the field of food legislation. They have recently joined with Austria, Portugal, Switzerland and the United Kingdom in a study of a plan for a "European Free Trade Association," generally called the "Outer Seven" to distinguish them from the six "Common Market" countries. All of the "Outer

Seven" are members of the European Food Code Council with the exception, so far, of the United Kingdom.

The other members of the council are Spain, Greece and Turkey which so far (as of August 24, 1959) did not belong to any economic group but are "Western-oriented" politically and, finally, four countries with Communist governments, namely the German Democratic Republic (East Germany), Poland, Hungary and Yugoslavia. The factual cooperation between representatives of West Germany and East Germany in the European Food Code Council was made possible by their acting as "technical experts" and advisers in committees and at the conference table and not as "official" delegates which could have been interpreted as mutual diplomatic recognition by the two governments. As long as the draft of the food code is in a preliminary stage, this delicate political problem can be ignored. It will become acute when the preliminary draft has been completed and is submitted to the conference for a formal vote. At the recent meeting in Vienna a delegate from Israel actively participated in the discussion of the council, which may make an interesting precedent for the admission to membership in the European Food Code Council of non-European nations with similar eating habits.

The first formal meeting of the council took place in Vienna in June, 1958. After adopting the provisional charter and bylaws, the conference appointed five subcommittees to study and prepare a report and preliminary draft on certain chapters of the European Food Code. At the second formal meeting held in Vienna in May, 1959, such preliminary reports were submitted and discussed.

Subcommittee on "General Principles."—The subcommittee on "general principles" was under the chairmanship of Mr. Forschbach (an official of the Ministry of Interior of Federal Republic of Germany). He submitted a preliminary report with 15 "guiding principles" which are to govern a legally acceptable international trade in food products between the member nations.

The protection of the consumer from health hazards and economic exploitation was to be the most important task of the code. During the transition period and while a great diversity still exists in the food laws of the various countries, special rules would apply to guarantee to the inhabitants of all countries an equal minimum of protection against the importation of objectionable foods. Certain definitions for the terms "harmful," "spoiled," "adulterated," "misleading" and

"added foreign substances" were recommended. At the same time the subcommittee recommended to make an exhaustive comparative study of the food laws of all European countries as a basis for a more elaborate draft of "guiding principles." This recommendation was unanimously adopted by the conference, which further requested the subcommittee to prepare a recommendation on how to subdivide and organize the code.

Subcommittee on Colors and Preservatives.—The subcommittee on colors and preservatives was under the chairmanship of Mr. Souverain (Department of the Repression of Frauds of France). The report emphasized the need to include a special chapter in the code which would set forth some general rules for the use of chemical additives. Such general rules or principles had already been recommended by several international organizations and had the subcommittee's full endorsement, namely, (1) *First Report of the Joint FAO/WHO Committee on Food Additives (1956)*, WHO Technical Report Series No. 129 and FAO Nutrition Meetings Report Series No. 15; (2) *International Union Against Cancer "ACTA,"* Vol. XIII (1957); (3) *Report of the Third Meeting of the Permanent European Research Committee for the Protection of the Population Against Long-Range Poisoning, ASCONA*, pages 13-17.

The subcommittee submitted a temporary definition of the term "preservative substances" limiting it to substances which prevent harmful changes in foods due to the action of micro-organisms. It also recommended the compilation of a positive list of permissible preservatives based on a study of the positive lists approved by the leading international organizations.

The subcommittee further submitted a definition of "colors," and recommended the compilation of a positive list of permissible colors based on a study of the positive lists approved by the leading international organizations. The conference adopted the recommendations of the subcommittee but, at the same time, resolved to split the subcommittee by constituting two separate subcommittees on colors and preservatives respectively (both under the chairmanship of France) and to set up an additional subcommittee on "other food additives" under the chairmanship of Federal Republic of Germany.

Subcommittee on Edible Fats and Oils.—A preliminary report on edible fates and oils was submitted by the Swiss chairman of the subcommittee, Professor Dr. Högl. The President recommended to

include synthetic oils in this chapter but to make butter and margarine the subject of a separate chapter, and to submit a draft for such two chapters to the next meeting of the conference.

Subcommittee on Mushrooms.—The Polish chairman of the subcommittee on mushrooms, Professor Dr. Krauze, submitted a preliminary report and recommended the compilation of a positive list of edible wild mushrooms which are so important in nutrition in many European countries. Poland already has an approved list of 31 mushroom species, Eastern Germany a list of 39 and the Soviet Union a list of 79. The subcommittee was commended for its report and requested to continue its studies.

Subcommittee on "Taking of Samples for Analysis."—The Austrian chairman, Dr. Lustig, submitted a complete preliminary draft of a chapter prepared by the subcommittee on "the taking of samples for analysis." The conference resolved to invite all member nations to submit their comments on this draft before October 1, 1959, with the idea that a final draft could be prepared and submitted to voting at the next conference in 1960.

This brief summary shows that the European Food Code is still in a very preliminary stage, but that the work on it is gaining momentum and that substantial progress can be expected to take place in the months to come. **[The End]**

REFERENCES

(1) Julius G. Zimmerman, "International Aspects of Food and Drug Legislation," 12 *Food Drug Cosmetic Law Journal* 402 (July, 1957).

(2) C. R. Shabetai, "Codex Alimentarius Europaeus," 13 *Food Drug Cosmetic Law Journal* 343 (June, 1958).

(3) Carlos A. Grau, "Food Additives and Cancer," 13 *Food Drug Cosmetic Law Journal* 350 (June, 1958).

(4) Julius G. Zimmerman, "Progress of Foreign Food Laws," 14 *Food Drug Cosmetic Law Journal* 189 (March, 1959).

(5) Carlos A. Grau, "Speech of Acceptance upon Receiving The Food Law Institute Award," 14 *Food Drug Cosmetic Law Journal* 318 (May, 1959).

(6) Jorge E. O'Farrell, "The Importance of Uniform Legislation for the American Nations in the Field of Food Products," 14 *Food Drug Cosmetic Law Journal* 451 (July, 1959).

(7) Enrique E. Bledel, "Necessity of Promoting Specialized Studies of the Food, Drug and Cosmetic Law in the Professional Organizations and Study Centers of Latin America," 14 *Food Drug Cosmetic Law Journal* 458 (July, 1959).

Opening of the Detroit Office of the Food and Drug Administration—Dedication of the George Potter Larrick Building

By EDWIN L. HARDING

Mr. Harding Reports on Ceremonies at Detroit, Michigan, on May 14, in Connection with the Opening of the New Detroit District of the United States Food and Drug Administration. The Two-Story, Well-Equipped Headquarters Is the First FDA District Office to Be Opened in 25 Years

ON MAY 14, 1959, a historic event occurred in Detroit, Michigan, in the opening of a new district office and laboratory by the United States Food and Drug Administration. This was the first new FDA district headquarters in 25 years, and it is another accomplishment resulting from a citizens Committee's appointment by Oveta Culp Hobby in 1955 to study the FDA and make recommendations for its future work.

The FDA has 16 other district offices. The Detroit office is the *second largest* FDA office in the country. It serves the State of Michigan and the northern judicial districts of Ohio and Indiana, with a total population of about 15 million. Before the opening of the Detroit office these areas were served by the Chicago and Cincinnati offices.

Mr. George T. Daughters is the Chief of the new district. Mr. Daughters is a career man of the FDA, having been with it more than 30 years. He began his FDA service as a chemist in San Francisco District. He became an inspector at Salt Lake City in 1930; was promoted to chief inspector; and served at Denver, Los Angeles, San Francisco, New Orleans and St. Louis. Then he served as Chief of

The Author, of Battle Creek, Michigan, Serves as Vice President and General Counsel of Kellogg Company

Baltimore District and, later, as Chief of Chicago District. He is certainly well qualified to direct this new important district.

$1 Million Facility Described

You will be interested to know that the building for the new district office was built by private enterprise and leased to the government. It is a beautiful two-story building, with well-equipped laboratories. It contains 24,000 square feet, and is located at 1560 East Jefferson Avenue. It is the first building ever to be especially designed for FDA work, and houses 80 persons, including 22 chemists, 37 inspectors, 17 clerks, and four persons in administration. In addition to offices, it includes a conference room, a library, seven special-purpose laboratories, two large chemical laboratories, one natural-light laboratory for color work in food additives and pesticides, and a bacteriological unit. The cost of the facility was slightly over $1 million including the special government equipment installed.

In view of the historical importance of this event, it was deemed advisable to have formal dedicatory ceremonies. An open house was held at the new building from 1:30 to 4:30 p. m. on May 14, and guided tours were conducted to show the typical work being done there. At 4:30 p. m., the official dedication ceremonies began. Approximately 300 food, drug, civic and government leaders from the United States and Canada attended the dedication. Mr. Daughters acted as master of ceremonies and Detroit's mayor, Louis Miriani, welcomed the office to Detroit.

Dr. Arthur S. Flemming, the Secretary of the Department of Health, Education, and Welfare, stated in part, in addressing the meeting:

I am sure that most of the consumers of this country have very little idea of how much they are indebted to the Food and Drug Administration.

There is no agency in the executive branch of the Government that gives more protection to the average citizen of this country than the Food and Drug Administration.

. . .

Above all this afternoon, I am delighted to be here because of the fact that this building is going to carry the name of the man who heads the Food and Drug Administration.

He symbolizes in a very, very real way the spirit of the Food and Drug Administration. He has dedicated his life to the service of his fellow citizens. He has always been willing to travel the second mile in your behalf and in my behalf.

I know of no finer example of what the career Civil Service means to our nation today than the career of George Larrick.

I regard him as one of a few very top civil servants and there is nothing—I really find it very difficult to find words to express my own appreciation for the kind of service that he has rendered and is rendering; on behalf of the United States Government, I am delighted to be here on this significant occasion, delighted with the building, but I am more than happy to be here for the purpose of paying tribute to the spirit of dedication of the Food and Drug Administration and above all, to pay tribute to the man who heads that Administration and to whom all of us are deeply indebted.

Plaque Unveiled by Bradshaw Mintener

Mr. Bradshaw Mintener, former Assistant Secretary of the Department of Health, Education, and Welfare, unveiled the plaque dedicating the building as "George Potter Larrick Building," saying in part:

George P. Larrick is the one we are honoring today. As we pass into this building, we will be ever mindful of the career of George who has given thus far thirty-six years of his life and is, in my mind, one of the top law enforcement officers of this country, and as Dr. Flemming has said, has done so much already to protect the safety and the welfare of our citizens.

Mr. George P. Larrick, Commissioner of Food and Drugs, responded in part as follows:

You know I got a little bit confused for a minute. I thought we came out here to dedicate a building rather than Larrick.

Seriously, this is an important building, Mr. Secretary, and Mr. Mintener and Mr. Daughters, as some of the previous speakers have said, it is the first time in the history of the Food & Drug Act which started 'way back in 1906 that a building was built, designed and equipped to do solely a job of protecting the public in the food, drug and cosmetic supplies.

So this building is a landmark in the Food and Drug history. It is important, a leader in Detroit with your growing industry, at a time when you are opening this new seaway, but the building has much more significance than that. It is going to be a prototype and a type of building that we hope to build throughout the United States and in the various places where we have laboratories to do this job. We are very grateful to everybody who has helped to make this achievement possible.

All that has been said today makes me feel very humble, but very proud, and I am very pleased to have this building bear my name.

The ceremonies were continued at a dedication banquet at the Sheraton-Cadillac Hotel in the evening, where introductory remarks were made by Mr. Harry J. Loynd, president of Parke, Davis & Company, with responses by Mr. Larrick and Mayor Miriani. The Honorable G. Mennen Williams, Governor of Michigan, was the speaker for the occasion.

CONSULTING FIRM REPORTS ON FDA ORGANIZATION, STAFFING, PROGRAM FUNCTIONS

A national management consulting firm has concluded that the United States Food and Drug Administration is effectively organized to carry out its responsibilities and has made a number of proposals for further strengthening FDA's inspection, testing and regulatory activities, according to an announcement by Secretary of Health, Education, and Welfare Arthur S. Flemming on October 14. The survey was made last spring at FDA's request.

Secretary Flemming said:

"I am gratified that the report finds the Food and Drug Administration suitably organized to carry out its important role in protecting the health of the American people from adulterated and misbranded foods and drugs. The study clearly recognizes the growing demands being made upon the Food and Drug Administration by the development of new products and manufacturing processes, and reaffirms the 1955 recommendation of a Citizens Advisory Committee for additional manpower in the field."

Some of the study's principal recommendations or conclusions dealt with the district office plan, district office operations, future field staff requirements, and relationships with the HEW regional offices and other constituent agencies.

In its appraisal of the district office plan, the study noted:

(1) The present system of FDA districts should be continued because it appears best adapted to the administration of the program.

(2) The number of resident inspection posts—and the staff in each—should be increased.

(3) All drug analyses should be assigned to districts where they can be most economically handled. At present, all 17 district laboratories conduct drug analyses, but the number and type vary widely, depending upon the number of drug manufacturers in each area.

The study's appraisal of district office operations disclosed, in part: Work plans and program management can be made more effective by stating objectives in terms of the percentage of compliance to be achieved in each industry; improving information on the number of firms subject to FDA regulation; developing more specific performance standards for inspectors and analysts; and assigning greater responsibility to district Chiefs in program planning and giving them more authority for independent action.

Foreign Law Comment

By JULIUS G. ZIMMERMAN

New Food Code Promulgated in Chile

The official gazette *(Diario Oficial de la Republica de Chile)*, Issue No. 24,395 of July 18, 1959, published a presidential decree—No. 176—dated February 25, 1959, which approved a new general food regulation *(Reglamento General de Alimentos)* based on the delegation of authority contained in Article 166 of the decree-law of May 29, 1931 (sanitary code). The new regulation is, in fact, a comprehensive food code, consisting of 801 articles. Its purpose was to replace and codify the many individual decrees and regulations on the subject of foods and beverages issued between 1932 and 1958, and listed in Article 801, which are specifically abrogated. The new food code was to become effective on the date of its publication, July 18, 1959, but a subsequent decree—No. 662—published in the *Diario Oficial*, No. 24,437, of September 8, 1959, postponed the effective date of Decree No. 176 for six months from September 8, 1959—until March 8, 1960.

A modernization and codification of the food law has been a project of long standing in Chile, and the size and wide scope of the new food code indicates the importance which the drafting committee of the government attached to it. It seems that the Chilean code was drafted independently from the Latin-American Food Code, which was approved by the Seventh Latin-American Chemical Congress, in Mexico City in April, 1959, and recommended as a uniform code for all Latin-American republics.

The new Chilean Food Code is subdivided as follows: Section I, "General Provisions," Articles 1-22; Section II, "Definitions and Standards"—Chapter 1, "Food Products in General," (1) "Definitions," Articles 23-28, (2) "General Provisions," Articles 29-37 and (3) "Containers and Packaging," Articles 38-65, and Chapter 2, standards for individual food products in alphabetical order, Articles 66-344 (this list includes food colors (Articles 148-155), preservatives, and

other additives); Section III, "Food Manufacturing Establishments," Title 1, "Production of Foods," Chapter 1, "Milk," Articles 345-387, Chapter 2, "Meat," Articles 388-445, Chapter 3, "Fowls," Articles 446-481 and Chapter 4, "Oysters," Articles 482-513, and Title 2, "Manufacturing Premises and Warehouses," Chapter 1, "General Provisions," Articles 514-553 and Chapter 2, "Types of Foods and Beverages," Articles 554-762, and Title 3, "The Sale of Food in Vehicles for the Transportation of Passengers," Articles 763-764; Section IV, "Transportation, Distribution and Ambulant Sales," Chapter 1, "Transportation," Articles 765-779, Chapter 2, "Ambulant Sales," Articles 780-784 and Chapter 3, "Importation and Exportation," Articles 785-794; Section V, "Sanitary Control," Chapter 1, "Inspection, Taking of Samples, etc.," Articles 795-799 and Chapter 2, "Penalties," Article 800; and list of abrogated decrees and regulations, Article 801.

It is impossible to analyze the substantive provisions of the new code in detail within the framework of a brief survey. The most important changes affecting the food industry will probably be found in the very elaborate new labeling provisions (Articles 54-65). The technical impossibility of complying with them at once was primarily responsible for the extension of the effective date.

Article 29 provides that any food products or raw materials or ingredients for which standards of identity have been set by the new code must comply with these standards. Such items for which no standards have been set may be sold only in packaged form with a declaration of ingredients on the label. Articles 33 and 34 require approval of imported food products by the health department before they may be cleared by the customs.

MAURICE P. KERR, OF MINNEAPOLIS DISTRICT, ASSIGNED TO WASHINGTON OFFICE

Maurice P. Kerr, Chief of Minneapolis District of the Food and Drug Administration, is being reassigned to the agency's Bureau of Field Administration in Washington, it was announced on October 13. A. Harris Kenyon, chief inspector of Boston District, is being promoted to succeed Mr. Kerr at Minneapolis.

Mr. Kerr's first assignment at the Washington headquarters will be to supervise strengthening of the FDA's field organization. This will involve planning for a new district office at Dallas; improvement of performance standards for FDA inspectors and chemists; and development of methods measuring the extent of industry compliance with the Federal Food, Drug, and Cosmetic Act.

CHRISTOPHER COMMENTS—Continued from page 618

government employee for a press release and is of more than passing interest to food and drug lawyers. According to the facts, the acting director of an agency announced in a press release his intention of suspending employees for certain conduct. The Court ruled, five to four, that the official has an absolute privilege. The dissenters take the position either that the act here was not within the scope of duty (Stewart) or that such an official has only a qualified privilege (Brennan and perhaps the Chief Justice, although the latter's exact position is not clear). The majority says that as long as the official is reasonably within his scope of duty, the privilege is absolute. Mr. Justice Black writes:

> It is enough for me here that the press release was neither unauthorized nor plainly beyond the scope of . . . official business, but instead related more or less to general matters committed by law to . . . [the individual's] control and supervision.

Thus, malice is not material.

The basis for this holding is public need for free action by officials:

> . . . it has been thought in the end better to leave unredressed the wrongs done by dishonest officers than to subject those who try to do their duty to the constant dread of retaliation.

The argument against the the Court's position is that a wronged citizen has no redress via a libel or slander suit and, thus, officials are permitted to push citizens around. Against this, the Court balances the need for officials who can act in a free atmosphere without fear of lengthy or numerous libel suits. Thus, the occasional bad officer is left free in order to give the greatest freedom to the honest officers. The greater good—the need for freely acting public officials—is given the victory.

In judging the opinions of the Justices, one must not move too quickly in attaching the handle "liberal" to the dissenters and "conservative" to the majority. For one thing, Justice Black votes with the majority, and his record is clear. For another, one of the vital things in a democratic government is public information, and we hear in every administration much comment that the Executive branch keeps needed information from the public. Be that as it may, it is vital that public officials, even below Cabinet rank, communicate with the

public, either directly or by way of the press. We cannot keep informed if only the President and Cabinet members speak out. The maximum of contact between the public and the agency is desirable.

This, therefore, is not a debate between the liberals and the reactionaries. Rather, it is an honest difference as to what is needed. The Chief Justice apparently would grant the President such absolute immunity, but he would not give it to, say, the Food and Drug Administration. All the justices agree, in the abstract, that an official who acts from malice should be held liable. But the majority, seeing how this principle would in practice hamper the honest official and hinder the right of the people to know, hold that the greater good is to be served by protecting and encouraging the honest official.

Having said this, I may add that it still is disturbing to contemplate a public official who acts from malice being protected. On the other hand, it is also disturbing to contemplate the food and drug administrator, as might be the case, spending substantial time in courts defending himself for various public statements he makes; the fact that he wins all the cases is no answer if his job suffers or if he becomes timid. Lawyers know that you can lose cases that you "should" have won.

If lawyers learn any lesson from the law, it is that law generally works on averages and for the long term. People are put in jail on a test that does not require absolute certainty, and a defendant may be separated from his money and property in a civil suit by an even less-certain formula. Further, we learn the value of the word "relative." You can end railroad wrecks in one day merely by discontinuing all railroads. You can effectively end drunken driving by chopping off the head of every person so convicted. But, relatively speaking, the cure would be worse than the disease.

What we are after in the present case is a rule that will, relatively speaking and over-all, best serve the community, and through the years. Applying this test, it still may be that officials should have only a qualified privilege as to libel, but such a conclusion does not follow merely from looking at the occasional injured individual; it follows from an over-all view.

It may be that some sort of "right to be heard," as a remedy, would be helpful here—not a hearing, but a right to say your piece with equal immunity and in an equally prominent setting. This is a device to which lawyers might well give serious attention.

In Preparation . . .

to Give You Sure Answers to New Excise Tax Problems;
Reflects All 1959 Law Changes to Publication Date . . .

1960

U. S. EXCISE TAX GUIDE

- more value for your excise tax dollar
- handy for desk or brief-case use
- easy to read—easy to understand

Here is an authoritative, clear-cut explanation of federal excise taxes as they stand today—designed to provide prompt, concise answers to every-day questions on all phases of these taxes.

Helpfully covered are such pertinent and widely varying tax angles as: sales and transfers of stock; retailers' excise taxes on jewelry, toiletries and luggage; tax on real property sales; manufacturers' excise tax rates; rules on transportation taxes and admissions taxes; and many, many more. Just flip the page to the information you want—it's all there!

Supplementing the detailed explanations comprising the main body of the text are quick-finding tables of excise tax rates; handy lists of excise tax forms by subject matter and number; a Code section finding list; filled-in Form 720; and check lists of taxable and nontaxable items. In all, 448 pages.

Taxes and Topics Covered

- Retailers' Excise Taxes
- Manufacturers' Excise Taxes
- Facilities and Services
- Documentary Stamp Taxes
- Taxes on Wagering
- Playing Cards and Games
- Sugar, Coconut and Palm Oil
- Import Taxes
- Regulatory Taxes
- Alcohol and Tobacco Taxes
- Machine Guns and Other Firearms
- Returns, Payment of Tax, Refunds

Dependable—A Commerce Clearing House Publication

Place Your Advance Order Today . . .

To get your copies of this fact-filled guide to Excise Taxes, just fill in and mail the post-free, tear-off Order Card. Delivery promptly when ready.

CCH PRODUCTS COMPANY
BOOKS BY MAIL
4025 W. PETERSON AVENUE. CHICAGO 46. ILLINOIS

ORDER CARD

MAIL TODAY!

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

BUSINESS REPLY MAIL
NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY—

CCH PRODUCTS COMPANY
4025 W. PETERSON AVE.
CHICAGO 46, ILL.

ORDER CARD

MAIL TODAY!

CCH PRODUCTS COMPANY
4025 W. Peterson Ave.
Chicago 46, Ill.

Sirs: Send promptly, when ready, ... copies of 1960 U. S. EXCISE TAX GUIDE at prices quoted below, plus small postage and packing charge. (When remittance in full accompanies order, CCH Products Company pays postage and packing.)

1 to 4 copies, $5.00 ea.
5 to 9 copies, $4.50 ea.
10 to 24 copies, $4.00 ea.
25 to 49 copies, $3.75 ea.

☐ Quote prices on larger quantities with our imprint

☐ Remittance herewith ☐ Bill us

(Subscribers for CCH's Current Law Handybooks receive and should order only for extra copies.)

Signature & Title .....

Firm .....

Street Address .....

Attention .....

0114—895

City, Zone & State .....

(If ordering by letter or purchase order, please attach this card.)

A COMMERCE CLEARING HOUSE PUBLICATION